

AWARD NUMBER: W81XWH-14-2-0148

TITLE: A Goniometry Paradigm Shift to Measure Burn Scar Contracture in Burn Patients

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RECIPIENT: The Geneva Foundation  
Tacoma, WA 98402

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14. ABSTRACT Objective: To test more extensively a recently designed Revised Goniometry (RG) method and compare it to Standard Goniometry (SG) used to measure burn scar contracted joint angles for determining disability severity and function in a burn population. Hypothesis: Significant statistical differences in patient joint angle measurements will be found between SG techniques compared to RG techniques which incorporate CKM and CFU principles. Specific Aim 1: Statistically compare SG measurements obtained using the traditional technique versus the newly designed RG measurement method at seven joints of interest with a predilection to develop burn scar contracture. Specific Aim 2: To statistically associate the severity of burn scar tissue contractures goniometrically with the extent of CFU involvement. Specific Aim 3: To statistically document the influence that adjacent joint position has on goniometric results related to patient functional outcomes.					
15. SUBJECT TERMS Goniometry, burn scar contracture, burn					
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## 1. INTRODUCTION:

Goniometry (GM) is an accepted clinical and research practice to assess patient outcome in terms of joint range of motion (ROM). Cutaneokinematic (CKM) research has documented that skin is recruited from areas distant to joint movement, and that adjacent joint positions also influence skin recruitment. While standard GM has been described as reliable in burns, scarring can affect GM results based on patient positioning thereby leading to questions concerning the validity of standard GM as a measure of patient functional outcome for patients after burn injury. The current research investigation is aimed at critically assessing standard GM compared to a new paradigm of revised GM based on CKM factors.

## 2. KEYWORDS:

Burn, Goniometry, Range of Motion, Scar, Contracture

## 3. ACCOMPLISHMENTS:

### What were the major goals of the project?

#### Task 1. Administrative Undertakings

##### 1a. Finalize research protocol: (GF; ISR; UCD; CS) Month 1

Resolve outstanding issues related to the study protocol at individual clinical sites.

- *Completed (8-20-15)*

##### 1b. Finalize facility contracts: (GF) Months 1-2

Individual contracts between The Geneva Foundation and each participating clinical site will undergo final negotiation and receive final signature by both parties.

- *50% complete (4/8 centers)*

##### 1c. Fabrication of foam measurement supports: (ISR) Months 1- 2

For the study, position blocks made of foam and cut to angles specific to attain positions addressed by the Revised Goniometry positions for knee flexion, knee extension and ankle dorsiflexion will be made available to all clinical sites for use in testing subjects.

- *Completed (11-14)*

##### 1d. Protocol Regulatory Review – local and DoD: (GF; ISR; UCD; CS) Months 1- 4

Final approval of the protocol at both the local and secondary level will occur.

- *In progress. ISR, ARK in progress with secondary review; UCD, UOC, HOP in progress with local IRB; REG, UOI, LSU, UNC in process of submitting to local IRB. Reference for site abbreviations in Appendix B.*

##### 1e. Develop Standard Operating Procedures (SOP) Manual: (ISR; UCD) Months 1 – 4

The SOP for the study detailing the procedures will be written finalized. Contents will address study and subject binders, data collection requirements including photographs of proper subject positions and goniometer placement, creation of Surface Area Graphic Evaluation diagrams, data submission, and study close-out.

- *Completed 8-12-15, now referred to as Manual of Operating Procedures (MOOP)*

**1f. Test data submission mechanism: (ISR; UCD) Months 2-3**

Beta testing of data submission will be trialed.

- *Completed (3-31-15)*

**1g. Organize arrangements to host Study Training Conclave: (GF; ISR; UCD) Months 1 – 4**

Site visits to potential host sites and negotiations between The Geneva Foundation and select host sites in San Antonio TX will be finalized.

- *Completed (29-30 Sept 14)*

**Task 2. Establish Research Systems Operations**

**2a. Conduct Training Conclave: (GF; ISR; UCD; CS) Month 4**

Two-day Developmental Meeting with representatives from participating clinical sites. The Agenda will consist of background and supporting information for the study; explanation with rationale for the Revised Goniometry subject positions with respect to cutaneokinematics and differential diagnosis of soft tissue joint limitation of motion; practice and assessment of attendees positioning and goniometry measurement techniques.

- *Completed (18-19 Nov 14)*

**2b. Conduct On-site Training: (ISR; UCD; CS) Month 5**

One-day in-person training by either the Principal Investigator or lead Associate Investigator of all personnel at clinical sites who will be involved in the research consisting of study procedures to include goniometry techniques, instruction and practice in creating of SAGE diagrams, and data submission.

- *In progress (2/8 sites complete: UCD 7-8 Oct 15, ARK 15 Oct 15)*

**Task 3. Data Collection / Audit / Analysis**

- *Screening, enrollment and data collection is lagging behind original schedule due to unanticipated delays in protocol approval.*

**3a. Begin subject screening and data submission: (ISR; UCD; CS) Month 6 – 18**

Each CS is estimated to contribute 18 subjects to the data pool  
Anticipated quarterly enrollment: 38 subjects

**3b. Begin and continue data audit: (ISR; UCD) Months 6 – 18**

Data records will be reviewed for accurateness as they are submitted in real time and in an on-going basis to detect and remedy any errors rapidly.

**3c. Conclude data submission: (ISR; UCD; CS) Month 18**

**3c. Begin and continue on-going data analysis: (ISR; UCD; CS) Months 7 – 18**

Data will be monitored by concurrent audits. An interim analysis will occur after the first 163 measurement comparisons is submitted and cleared. Data collection will cease at the time that statistical significance is achieved for both the primary sites of interest and for the group aggregate. Subsequent interim analyses will occur in blocks of 45 measurement pairs. Data will be analyzed by comparing the standard to the revised goniometry measurements using repeated measures ANOVA. This process will be performed for the entire data set as well as individual joint subsets. Correlations will be performed between the severity of joint limitation and the percentage of cutaneous functional unit involvement.

**3d. Finish data analysis: (ISR; UCD) Months 18 – 21**

With the anticipation that all needed data will be collected within the budgeted twelve months for data collection, and should statistical significance not be achieved prior to this time, final data analysis will be conducted.

**Task 4. Data Reporting**

#### **4a. Begin data report organization: (GF; ISR; UCD; CS) Months 21 – 22**

Collected and analyzed data will be collated. Study results will be shared with contributing partners in terms of interpretation and reporting. Abstract(s) will be prepared for submission to meet deadlines for presentation at appropriate professional meetings.

#### **4b. Manuscript preparation and submission: (GF; ISR; UCD; CS) Months 23 – 24**

A seminal manuscript will be developed and submitted to an appropriate professional burn-related journal.

### **What was accomplished under these goals?**

#### **Task 1. Administrative Undertakings**

##### **1a. Finalize research protocol – Completed Q4**

- Core protocol was approved Q4 (8-20-15) and sent to participating sites (8-21-15)

##### **1b. Finalize facility contracts – In Progress**

- Clinical Trials Agreements executed between Geneva and 4/8 participating sites
- Cooperative Research and Development Agreement (CRADA) agreements established between ISR and 4/8 participating sites.

##### **1c. Fabrication of foam measurement supports – Completed Q1**

- Foam wedges for modified positions designed, tested, fabricated and distributed to participating sites (Oct-Nov 2014)

##### **1d. Protocol Regulatory Review – In Progress**

- Core protocol approval received (8-20-15)
- ISR amendment to the core protocol currently under review with HRPO
- ARK local IRB approval received (9-1-15) and currently under secondary review with HRPO
- UCD, HOP, UOC have submitted their protocols to their local IRB
- REG, LSU, UOI and UNC in progress of submitting protocols to local IRB

##### **1e. Develop Standard Operating Procedures (SOP) Manual – Completed Q4**

- During protocol review, feedback was provided to change the SOP to “Manual of Operating Procedures” now referred to as MOOP.
- The MOOP was completed Q4. Please see Appendix C.

##### **1f. Test data submission mechanism – Completed Q3**

- Beta testing of data submission using the Safe Access File Exchange (SAFE) test site for submission of data between participating sites and ISR complete with 8/8 centers.

##### **1g. Organize arrangements to host Study Training Conclave - Completed Q1.**

- Pre-planning meeting for Conclave held with principle and primary co-investigator (29-30 Sept 14)
- Lectures on Cutaneouskinematic, Differential Diagnosis and Test Positions developed using Power point.
- Agenda of lectures and practice workshops was created
- Development of a set of laminated reference cards with photos and descriptions of standard and revised goniometry positions. Three 2-hour photo shoots were conducted and the photos/descriptions were revised multiple times for clarity.
- Specs tested and confirmed for equipment (bolsters)

- A reliability criterion computer program was developed using excel (example below) to verify and standardize competency with goniometry measurements
- Randomization Table Agenda developed:

***Goniometry Measurement Randomization Table***

Body Region	Is the Patient Eligible for GM Measurement in the Body Region?	Eligibility Status	Random Number	Body Region Order	First GM Measurement
	Yes/No				
Neck Extension	N	Non-Eligible	NA	NA	NA
Shoulder Abduction	Y	Eligible	0.447878517	4	Standard
Shoulder Flexion	N	Non-Eligible	NA	NA	NA
Elbow Flexion	N	Non-Eligible	NA	NA	NA
Elbow Extension	N	Non-Eligible	NA	NA	NA
Wrist Flexion	Y	Eligible	0.656294653	3	Revised
Wrist Extension	Y	Eligible	0.02860599	5	Revised
Knee Flexion	N	Non-Eligible	NA	NA	NA
Knee Extension	N	Non-Eligible	NA	NA	NA
Ankle Dorsiflexion	Y	Eligible	0.831524794	2	Revised
Ankle Plantarflexion	Y	Eligible	0.884784562	1	Revised

- Mannequin models obtained and positioned for gold standard measurements to be used for reliability testing.
- Travel arrangements made for attendees from 8 participating sites.

## **Task 2. Establish Research Systems Operations**

### **2a. Conduct Training Conclave - Completed Q2.**

- A two-day developmental meeting (18-19 Nov 14) with representatives from all participating clinical sites was conducted at main site (ISR) for training and study preparation purposes. Training objectives met: included:
  - Educational lectures on study background and relevant information
  - Training and practice in the standard and revised goniometry positions
  - Distribution of study equipment including bolsters, goniometry reference text, laminated reference cards
  - Reliability testing of goniometry measurement methods within and between investigators. Reliability results example:

Revised Goniometry Measurement Criterion Validity					
				Gold Standard Measurement	Minimal Allowable Deviation
				45	3
Rater	Measurement			Mean	Pass/Fail
	1	2	3		
1	44	42	43	43.0	PASS
2	44	42	40	42.0	PASS
3	49	43	41	44.3	PASS
4	48	50	45	47.7	PASS
5	43	44	44	43.7	PASS
6	48	45	44	45.7	PASS
7	44	43	44	43.7	PASS
8	42	42	44	42.7	PASS
9	44	44	43	43.7	PASS

## 2b. Conduct On-site Training: In Progress

- Training at UCD complete 7-8 Oct 15
- Training at ARK complete 15 Oct 15
- Training included protocol review, training with MOOP for study procedures, SAGE diagram training and test, review of CRFs and data submission process, review of patient positions, and evaluation of physical setting.
- Site training checklist developed (Appendix E)

## What opportunities for training and professional development has the project provided?

### Training

- Study lead investigators determined gold standard measurements during pre-conclave work to provide reliable means of determining goniometric measurements in a uniform manner.
- On-site trainings in progress to develop proficiency with the use of study tools (SAGE diagrams, goniometric techniques).

### Professional Development

- The study Conclave with investigators from participating sites provided didactic and hands-on training in cutaneokinematics and goniometric techniques.



- Monthly teleconferences provide the opportunity for small group discussion regarding techniques and study procedures.
- Goniometry books – Norkin and White (FA Davis, 2009) text books were purchased for each site as a reference manual for standard goniometric techniques.

### **How were the results disseminated to communities of interest?**

Nothing to Report

### **What do you plan to do during the next reporting period to accomplish the goals?**

Due to the protracted time for protocol approvals, significant delays have been encountered for screening, enrollment and data collection. Now that the core protocol has been approved, participating sites are able to process local protocols and submit for secondary approval through HRPO. Subsequently, screening, enrollment and data collection/analysis/reporting is anticipated to begin without further set-backs in the next quarter.

### **Task 3. Data Collection / Audit / Analysis**

#### **3a. Begin subject screening and data submission:**

- Once primary and secondary IRB approval is received, each site will begin screening subjects and enrolling.
- Tele-conference calls are being conducted to monitor site progress with enrollment – Appendix D. The first tele-conference call was 2 Oct 15 and will be held monthly throughout the study period.
- Each site is estimated to contribute subjects to the data pool accordingly:

Facility	Estimated number of annual burn out-patients	Estimated proportion of patients meeting inclusion criteria	Estimated proportion of patients agreeing to participate	Estimated number of patients lost to follow-Up	Anticipated number of enrollees x contracture sites
U. S. Army Institute of Surgical Research	120	60	40	4	$36 \times 2 = 72$
University of California – Davis	80	40	27	3	$24 \times 2 = 48$
University of Colorado	33	17	11	1	$10 \times 2 = 20$
University of Iowa	57	29	19	2	$17 \times 2 = 34$
Regions Hospital Burn Center	39	20	13	1	$12 \times 2 = 24$
University of North Carolina – Chapel Hill	45	23	15	2	$13 \times 2 = 26$
Louisiana State University – Shreveport	42	21	14	1	$13 \times 2 = 26$
Arkansas Children's Hospital	60	30	20	2	$18 \times 2 = 36$
John Hopkins Burn Center	93	47	31	3	$28 \times 2 = 56$

#### **3b. Begin and continue data audit:**

- Data records will be reviewed for accurateness as they are submitted in real time and on an on-going basis to detect and remedy any errors.

### **3c. Conclude data submission**

- Pace of enrollment and results of interim data analysis will dictate the duration of data collection necessary.

### **3c. Begin and continue on-going data analysis:**

- Data will be monitored by concurrent audits. An interim analysis will occur after the first 163 measurement comparisons is submitted and cleared.
- Data collection will cease at the time that statistical significance is achieved for both the primary sites of interest and for the group aggregate.
- Subsequent interim analyses will occur in blocks of 45 measurement pairs.
- Data will be analyzed by comparing the standard to the revised goniometry measurements using repeated measures ANOVA. This process will be performed for the entire data set as well as individual joint subsets.
- Correlations will be performed between the severity of joint limitation and the percentage of cutaneous functional unit involvement using Pearson's or Spearman's correlation coefficient.

### **3d. Finish data analysis:**

- Completion of data analyses will be in tandem with data submission and based on periodic interim analysis. Complete data collection is anticipated to need the budgeted twelve months. However, should statistical significance of the data be achieved earlier, this will be grounds for study termination as per the protocol.

## **Task 4. Data Reporting**

### **4a. Begin data report organization:**

- Collected and analyzed data will be collated.
- Study results will be shared with contributing partners in terms of interpretation and reporting.
- Abstract(s) will be prepared for submission to meet deadlines for presentation at appropriate professional meetings.

### **4b. Manuscript preparation and submission:**

- A seminal manuscript will be developed and submitted to an appropriate professional burn- related journal.

## **4. IMPACT**

### **What was the impact on the development of the principal discipline(s) of the project?**

#### **Impact:**

- Increase awareness of participating clinicians of the need for burn specific goniometric methods more relevant and useful for the burn population.
- Create awareness between disciplines (OT/PT) of the ways they've been taught to practice.

### **What was the impact on other disciplines?**

Nothing to report

### **What was the impact on technology transfer?**

Nothing to report

**What was the impact on society beyond science and technology?**

Nothing to report

**5. CHANGES/PROBLEMS:**

There have been no changes in approach.

**Actual or anticipated problems or delays and actions or plans to resolve them**

Delays have occurred with core protocol and consent approval. Protracted time to finalize and satisfy requirements for core protocol (including changing from a SOP to a MOOP format) and informed consent have led to unanticipated delays in participating site protocol approval and initiation of data collection.

**Changes that had a significant impact on expenditures**

Spending has been delayed due to core protocol approval delays. Now that core protocol has been reviewed and approved, spending will increase in parallel with on-site study training and remuneration for submitted data.

**Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**

Not applicable.

**6. PRODUCTS:**

- **Publications, conference papers, and presentations**

Related abstract submission for American Burn Association conference 2016: “Cutaneous Functional Units Predict ROM Recovery with Therapy” by co-investigator, I Parry and S Sen from UCD. Results of related study demonstrate correlation of CFUs to ROM and lack of correlation of standard goniometric techniques to functional measures of ROM.

- **Technologies or techniques**

Randomization Table and Reliability Table (inserted previously) developed by Jud Janek PhD, statistician at ISR.

- Randomization table created to avert selection bias as well as methodological bias.
- Reliability table created to establish minimum level of acceptable goniometric measure and ensure adequacy of measurements among clinicians.

**Other Products**

- Prototype goniometry bolster developed for patient positioning.
- Surface Area Graphic Evaluation (SAGE)— is a computerized burn wound mapping program with an electronic diagram originally patterned and formulated based on the Lund and Browder burn diagram. It specifically was customized to calculate and report the percentage of individual cutaneous functional unit areas.

## 7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

Name: Reg Richard, MS, PT  
Project Role: Principal Investigator - ISR  
person month worked: 13

Contribution to Project: Mr. Richard is principle investigator and responsible for overall study conduct and study oversight. He has developed and modified all study documents including the core protocol and informed consent as needed. He co-organized the Study Conclave as well as co-ordinated the initiation of CRADAs, SAGE modification, development and testing and SAFE testing.

Name: Ingrid Parry, MS, PT  
Project Role: Co-Investigator - UCD  
person month worked: 13

Contribution to Project: Ms. Parry helped develop study protocol and appendices and formulation of the MOOP. She worked with PI on coordinating investigator meetings and trainings and obtaining study equipment. She will monitor participating site enrollment, review data, assist in data analysis and writing of manuscripts for publication.

### **Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**

No change in personnel.

## 8. SPECIAL REPORTING REQUIREMENTS:

**QUAD CHARTS:** The Quad Chart (available on <https://www.usamraa.army.mil>) shall be updated and submitted as an appendix.

## 9. APPENDICES:

Appendix A – Quad chart  
Appendix B – Participating site abbreviations  
Appendix C – MOOP  
Appendix D – Enrollment Update  
Appendix E – Participating Site Training Checklist

# A Goniometry Paradigm Shift to Measure Burn Scar Contracture in Burn Patients

Log #13214017

Award #: W81XWH-14-2-0148



PI: Reg Richard, MS, PT

Org: U. S. Army Institute of Surgical Research/The Geneva Foundation

Award Amount: \$368,255

## Study/Product Aim(s)

- Specific Aim 1: To compare the average reduction in joint range of motion measured with the standard GM measurements to a newly conceived set of revised GM measurements in a burn population across six (6) joints of interest in eleven (11) single directions.
- Specific Aim 2: To compare the average reduction in joint range of motion measured with the standard GM measurements to a newly conceived set of revised GM measurements in a burn population for each of the six (6) joints of interest in eleven (11) single directions.
- Specific Aim 3: To examine the association between the reduction in the joint range of motion and the extent of cutaneous surface area involvement.

## Approach

The study is a prospective, multi-center, observational study comparing standard goniometric positions to revised goniometric positions to measure and document burn scar contracture.

## Standard Goniometry (SG) Position to Measure Wrist Extension



## Revised Goniometry (RG) Position to Measure Wrist Extension



This quarter accomplishments include SAFE system of data transmission trials and initiation of SAGE compatibility testing with participating sites. The protocol has received further review by ISR research regulatory compliance division and revisions continue. CRADA agreements have been executed with 4/8 (50%) centers and contract agreements are in place between Geneva and 2/8 centers.

Activities	FY	2014-15				2015-16			
		1	2	3	4	1	2	3	4
Facility contract negotiations/ system operations established									
Training conclave/on-site training									
Begin enrollment/data collection/audit/analysis									
Continue enrollment/data collection/audit/analysis									
Complete data analysis									
Begin data report organization									
Manuscript preparation/submission									
Estimated Budget (\$K)		\$67K				\$302K			

Updated: 15 Oct 2015

## Goals/Milestones

### CY14-15 Goal – Administrative Undertakings and Research Operations

- ☒ Finalize research protocol
- ☐ Finalize facility contracts
- ☒ Study start-up equipment obtained
- ☐ Protocol Regulatory Review
- ☒ Develop SOP (MOOP)
- ☒ Study Conclave
- ☐ CRADA agreements with participating sites
- ☐ Onsite training at participating centers
- ☐ Begin enrollment

### CY15-16 Goals – Data Collection, analysis and reporting

- ☐ Enrollment at all participating sites
- ☐ Data audited
- ☐ Data Analyzed
- ☐ Manuscript preparation and submission

## Comments/Challenges/Issues/Concerns

- None

## Budget Expenditure to Date

- Projected Expenditure: \$219K
- Actual Expenditure: \$66,864.81

**Participating Site Abbreviations:**

**ISR:** U. S. Army Institute of Surgical Research Burn Center

**UCD:** University of California, Davis

**HOP:** Johns Hopkins Bayview Medical Center

**ARK:** Arkansas Children's Hospital Research Institute

**UOC:** University of Colorado Hospital, Denver

**UOI:** University of Iowa Hospital

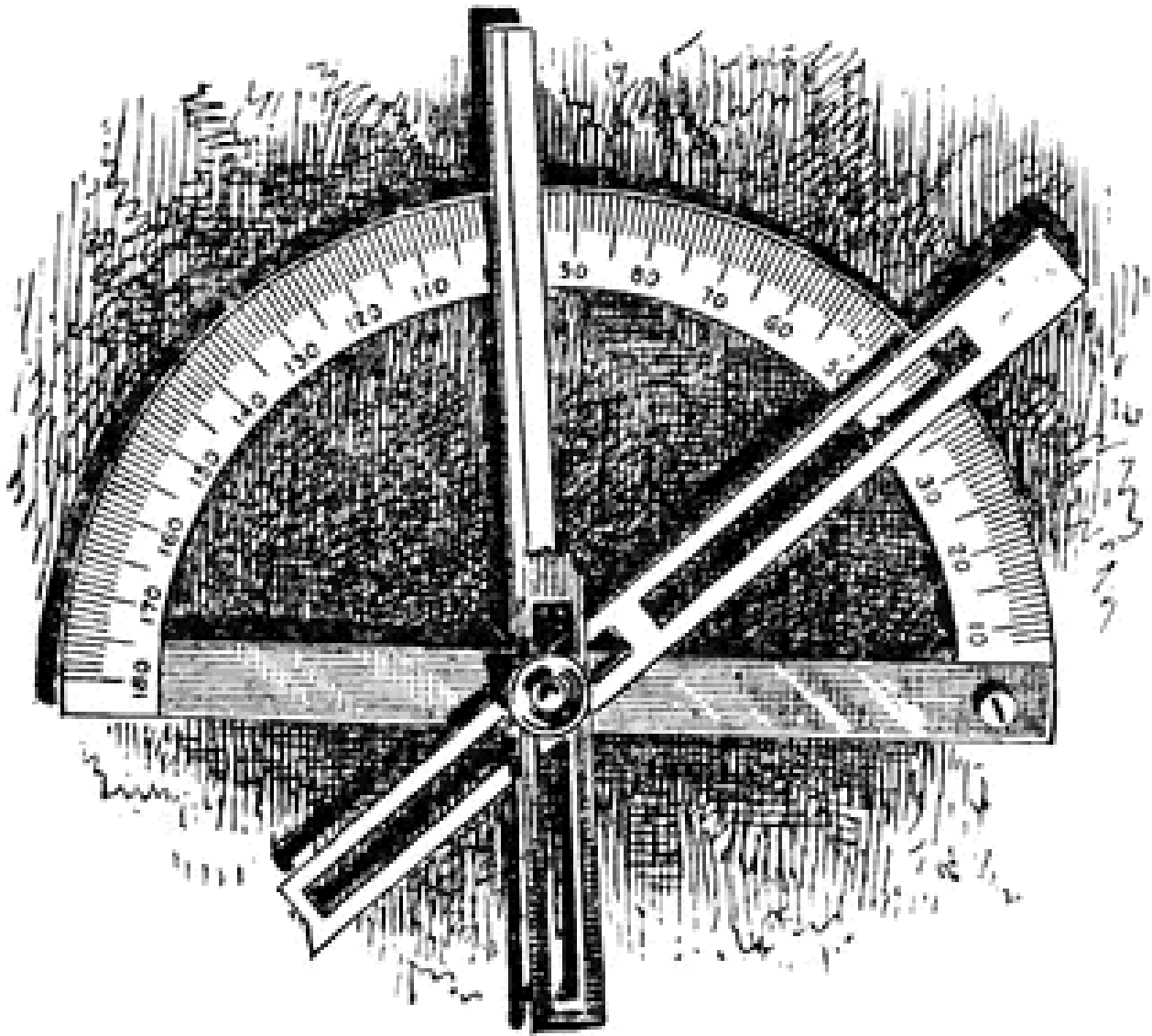
**REG:** Regions Hospital

**UNC:** University of North Carolina Hospital- Chapel Hill

**LSU:** Louisiana State University Health Sciences Center

# *Goniometry*

## *Study*



**Manual of Operating Procedures**

# **Manual of Operating Procedures (MOOP)**

**August 8, 2015**

## **STUDY: A Goniometry Paradigm Shift to Measure Burn Scar Contracture in Burn Patients**

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## **Abbreviation/Acronyms List**

AI	Associate Investigator
AMRDEC	U. S. Army Aviation & Missile Research Development & Engineering Center
CFU	Cutaneous Functional Units
CKM	Cutaneokinematics
CRF	Case Report Form
GM	Goniometry
HRPO	Human Research Protection Office
IRB	Institutional Review Board
LOM	Loss of Motion
MOOP	Manual of Operating Procedures
MRMC	Medical Research and Materiel Command
ROM	Range of Motion
PI	Primary Investigator
SAFE	Safe Access File Exchange
SAGE	Surface Area Graphic Evaluation
TBSA	Total Body Surface Area
USAISR	United States Army Institute of Surgical Research

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## SECTION 1. STUDY CONTACTS

### Administrative contact information

For study related questions, contact the principal investigator or associate investigator (see below).

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### Participating site contact information

<b>Facility</b>	<b>Administrative Contact</b>	<b>Clinical Contact</b>	<b>PI</b>
<b>U. S. Army Institute of Surgical Research Burn Center</b>		Reg Richard, MS, PT Lead Principal Investigator U.S. Army Institute of Surgical Research Fort Sam Houston, TX 78234-7767 (210) 916-5760 <a href="mailto:reg.l.richard.ctr@mail.mil">reg.l.richard.ctr@mail.mil</a>	Reg Richard, MS, PT Lead Principal Investigator U.S. Army Institute of Surgical Research Fort Sam Houston, TX 78234-7767 (210) 916-5760 <a href="mailto:reg.l.richard.ctr@mail.mil">reg.l.richard.ctr@mail.mil</a>
<b>Johns Hopkins Bayview Medical Center</b>	Dene Palazzi-Khan 4940 Eastern Avenue, P3-4-11 Baltimore, MD 21224- 2780 Email: <a href="mailto:dnoppen1@jhmi.edu">dnoppen1@jhmi.edu</a> Phone: 410-550-0886 Fax: 410-550-8161	Linda Ware, OT, CHT Rehabilitation Department 4940 Eastern Avenue Baltimore, MD 21224 Email: <a href="mailto:lware1@jhmi.edu">lware1@jhmi.edu</a> Phone: 410-550-0754 Fax: 410-550-1390	Dr. Leigh Ann Price 4940 Eastern Avenue, P3-4-11 Baltimore, MD 21224-2780 Phone: 410-550- 0886 Fax: 410-550-8161 Email: <a href="mailto:lprice13@jhmi.edu">lprice13@jhmi.edu</a>
<b>Arkansas</b>	Janet Storment	Mandy Yelvington, MS,	Mandy Yelvington

<b>Children's Hospital Research Institute</b>	ACHRI Clinical Trials Administrator #13 Children's Way, Slot 842 Little Rock, AR 72202 O- (501)-364-2760 F- (501)-978-6413 Email - StormentJanetS@uams.edu	OTR/L 1 Children's Way, Slot 104 Little Rock, AR 72202 Phone #: 501-364-1192 Email: yelvingtonml@archildrens.org Fax: 501-364-3564	(same)
<b>University of Colorado Hospital, Denver</b>	Julie Heerse Research & Business Development Administrator Dept. of Physical Medicine & Rehabilitation- CU School of Medicine Mail Stop F493 AO1 2nd Floor, Room 2508 12631 East 17th Avenue Aurora, CO 80045-0508	Matthew Godleski, MD matthew.godleski@ucdenver.edu Mail Stop F493 12631 East 17th Avenue Aurora, CO 80045 (o) 720-848-3809 (f) 720-848-3801	Matthew Godleski (same)
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<b>University of</b>	Mary Beth Lawless, MS,	Ingrid Parry, MPT	Soman Sen, MD

<b>California Davis</b>	RN Director of Research Operations UC Davis Data Coordinating Center Div. of Burn Surgery Shriners Hospital for Children Northern CA 2425 Stockton Blvd., Suite 555 Sacramento, CA 95817 Phone: 916.453.2133 Fax: 916.453.2139 marybeth.lawless@ucd mc.ucdavis.edu	Shriners Hospital for Children Northern California 2315 Stockton Blvd. Sacramento, CA 95817 P: 916-201-0736 email: giparry@surewest.net	Shriners Hospital for Children Northern California 2315 Stockton Blvd. Sacramento, CA 95817 P:(916) 453-2250 email:soman.sen@g mail.com
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## SECTION 2. STUDY PROFILE

### Background/Overview

Goniometry (GM) is the most common and widely used assessment method to measure patient Range of Motion (ROM) and subsequent severity of burn scar contracture in burn populations. Standard GM methods were founded on an orthopedic model of joint movement and the technique has been shown to be reliable in the burn population. However, joint limitation of motion (LOM) caused by burn scar contracture is based on an *integumentary or cutaneous* model; the hallmark difference being that natural skin is a single, continuous piece of tissue without joints. Standard GM fails to consider the cutaneokinematic (CKM) influence, or in other words, the effect of surrounding scar and skin on joint movement. Due to this biomechanical difference, the validity of current standard GM methods related to patient function with burn scars is questioned.

Fields of skin associated with joint movement have been identified as cutaneous functional units (CFUs) and have been found to extend great distances from a joint crease. Furthermore, adjacent joint position that either contributes or removes slack in the tissue has a direct impact on skin recruitment during ROM, especially in patients with restrictive burn scars. Additionally, skin or scar distant from a joint needs to be considered as a source of tissue recruitment or restriction when evaluating ROM. Standard GM methods do not account for the cutaneous biomechanical interaction between the position of adjacent joints and the need for scar tissue to accommodate positioning of the movement of two consecutive joints together. Therefore, the major difference that exists between standard GM and the suggested revised GM methods is the position of adjacent joints or limb segments when GM is performed. In the current study, the revised GM method removes slack from the surrounding tissue and mimics common positions of function. The results of this investigation are anticipated to provide an improved approach to document burn scar contracture as related to movement restriction and subsequent limitations in function.

## **Study Summary**

The study is a prospective, multi-center study utilizing a convenience sample of sequentially enrolled patients. Subjects will be tested at one time point only. Standard GM measurements will be compared to revised GM measurements. Anticipated outcome of the study will identify and document a more applicable method to measure joint ROM in both military and civilian burn survivors.

## **Study Hypothesis/ Aims**

*Hypothesis:* Compared to standard GM measurement methods, goniometric measurements using a set of revised GM measurements will show a lower mean difference in measuring limited joint range of motion.

### *Specific Aims:*

Specific Aim 1: To compare the average reduction in joint range of motion measured with the standard GM measurements to a newly conceived set of revised GM measurements in a burn population across six (6) joints of interest in eleven (11) single directions.

Specific Aim 2: To compare the average reduction in joint range of motion measured with the standard GM measurements to a newly conceived set of revised GM measurements in a burn population for each of the six (6) joints of interest in eleven (11) single directions.

Specific Aim 3: To examine the association between the reduction in the joint range of motion and the extent of cutaneous surface area involvement.

## **Explanation of procedures:**

- **Goniometry** – Goniometry is the measurement angles created by human joints. A measuring tool, called a goniometer is placed along the bones immediately proximal and distal to the joint being evaluated. For this study, goniometry will be done for the identified joint of interest with the body in two different positions, the standard GM

position and the revised GM position. The testing is described further in Section 5 and Appendix C.

- **Surface Area Graphic Evaluation (SAGE) diagram** – SAGE is an electronic graphic depiction of the location of burn scars. The program allows for identification of involved areas surrounding a joint and calculation of CFU involvement. Specific procedures for completing the SAGE diagram are described in Section 5 and Appendix L.
- **Digital photography** – Digital photography will be used to provide documentation of the area of burn scarring and used to complete or confirm the Surface Area Graphic Evaluation (SAGE) diagram. The investigator will use a digital camera to take pictures of the area(s) of interest per instructions in Appendix K. The photo should be in focus and appropriate lighting used for the given environment. Photos should be taken without revealing identifying information. Two photos of each site should be taken.

**Schedule of Procedures** – Subjects will undergo testing one time with no follow up needed. The testing session will occur within approximately two weeks of consenting, based on an equally convenient and agreed upon date and time by both subject and investigator. Testing will occur within one week of anticipated hospital discharge if the subject is an inpatient or during routine follow-up therapy appointment or clinic visit if he/she is an outpatient.

### **SECTION 3. STUDY ORGANIZATION**

**Responsibilities of Lead Principal Investigator and Associate Investigator** – The lead PI and AI will be responsible for overall coordination of the study. They will train primary personnel from each participating site on study procedures, data collection and data submission. They will communicate with the participating sites, providing updates regarding study progress and being available to address questions and concerns. They will coordinate and lead monthly phone conferences. The lead PI will audit the data for completeness and follow up via telephone or email with the participating site for clarification of information. The lead PI will ensure that all data is stored securely at the primary site and be responsible for interpretation, analysis and reporting of outcomes.

**Responsibilities of participating site personnel** – Participating site PIs and clinical staff will be responsible for identifying, screening, consenting, enrolling and data collection according to study protocol and MOOP. Immediately following testing of a subject the data will be submitted electronically to the lead site using the U. S. Army Aviation & Missile Research Development & Engineering Center (AMRDEC) Safe Access File Exchange (SAFE). The data will be complete and accurate to the best of the ability of local clinical staff. Primary personnel (those who received training at the Conclave and on-site visits) will be responsible for training new staff involved in the study at their site. All staff will be trained appropriately. Personnel at the participating site will be available for telephone discussions in the case of any clarification needed during audits. At least one staff member will attend monthly phone conferences and provide study progress information. It will also be the responsibility of the participating site staff to maintain the subject study folders and photographs in a secure manner.

**Study Binder** – Each site should create and maintain a study binder. At a minimum, contents should include:

- 1) Approval letter from local IRB and HRPO

- 2) Protocol – core and site specific addendum
- 3) Amendments to the protocol
- 4) Master HIPAA form
- 5) Master informed consent form
- 6) Continuing IRB reviews
- 7) List of reportable events in chronological order
- 8) Study documents (CRFs, MOOP, other documents)
- 9) General correspondence (emails, documentation of phone calls, minutes)
- 10) Miscellaneous documents (CVs, CITI training, COIs)

**Study Communication** - Frequent communication among the organizations and individuals involved in this study is essential for success. Communication may occur via email or telephone and should not include any patient identifying information. Please refer to the study contact list (Section 1) for contact information. Monthly conference calls will be conducted where the following will be discussed: status updates on current number of patients screened and enrolled at each center, concerns/ problems/ solutions for study implementation and the various sites, and audit status.

**Selection of Investigators and Study Staff** – Participating sites internally will determine appropriate staff for screening, consenting and testing subjects. Procedures will follow those outlined in this MOOP and the study protocol. Any staff testing subjects must meet regulatory requirements to participate in research and have completed the on-site training and be familiar with the standard GM and revised GM positions.

**Training** – The primary site will host a training conclave prior to the start of the enrollment. Each site will send one investigator to the main site (USAISR). The training will include education on background information, CKM, training on differential assessment of tissue restriction and the standard and revised GM positions. Attendees will practice the positions

and become familiar with the equipment. In addition, attendees will participate in establishing reliability and validity table for the various positions (Appendix B).

After the core protocol has been approved by both MRMC-IRB and Human Research Protection Office (HRPO) and the protocol has been submitted to the local IRBs, the lead investigator or associate investigator will visit each participating site to do a more detailed on-site training. This on-site visit will include training in the study protocol for clinicians who will participate locally, training and testing of access to SAGE, practice transfer of data using the SAFE site, and set-up of study binders/folders. Assessment of equipment and environment at the local participating site will also occur.

## **SECTION 4. SCREENING, ENROLLMENT, WITHDRAWAL**

**Recruitment Strategies** - Informational flyers (Appendix I) may be placed in various locations to make patients aware of the study. These patients will be able to contact the PI or AI directly using the flyer information to set up a time to learn more about the study.

**Subject Screening and Enrollment** - Subjects may be considered for the Goniometry study only after the participating site has received both local institutional Review Board (IRB) AND secondary approval from Medical Research and Materiel Command (MRMC) Human Research Protection Office (HRPO).

Process:

1. Adult patients will exhibit a limitation of motion (LOM) at one of the joints of study interest.
2. Patient will be approached as to their level of interest in study participation.
3. If patient expresses interest, the study will be explained in detail at an understandable level.
4. If the patient interest continues, s/he will be given an Informed Consent and HIPAA form to sign after both have been reviewed and explained.
5. If patient signs both the Consent and HIPAA forms, the patient will be evaluated per the Inclusion/Exclusion criteria. Enter information per the Goniometry Study Eligibility Log (Appendix H).
6. If the patient passes the evaluation, s/he will be enrolled into the study. A Study ID# will be assigned and recorded on Appendix H.
7. If for some reason the subject decides to withdraw from the study, the eligibility status is changed to NA indicating an 'Off Study' status. The Study ID# stays assigned to the subject and is not re-used.

**Eligibility Log** - Information about subjects who agree to participate is recorded as follows on the Screening Log (Appendix H).

1. After the subject has consented to participate in the study, the screen date will be recorded (this date must be on or after the consent date).
2. The subject's last name, first name will be logged.
3. The Study # is assigned and logged.

Version 1 08AUG2015  
**Appendix H**  
(This form should be kept at the local site and destroyed at completion of the Goniometry Study)  
**Goniometry Study Eligibility Log**

Inclusion Criteria	Exclusion Criteria
18 through 80 years of age	< 18 years or > 80 years of age
Burn scar contracture associated with a primary or secondary area of interest	perforated ROM due to soft tissue restriction other than burn scar tissue as the primary limiting factor
Minimum loss of motion (ROM) at point of interest per Appendix A	Acute pain, as expressed by the subject, emanating from scar tissue preventing full available passive ROM
Presence of a burn scar contracture as the principle soft tissue limiting joint ROM	ROM previously associated with open wound within (2") area of interest
	joint ROM less than minimum listed in Appendix A
	Patients with neurologic, muscular or skeletal condition affecting a joint of interest, e.g. spasticity, arthritis, history of joint dislocation
	Patients with a medical history or diagnosis of fibromyalgia or dermatologic condition such as psoriasis, lupus, scleroderma
	Patients that have a ROM associated with a joint area of interest that has had a surgically-released tissue flap

In order to be eligible for this study, the patient must meet all of the inclusion criteria and none of the exclusion criteria

Screen Date	Name	Study ID#

**Subject Numbering** - Every subject enrolled is assigned a Study ID# which is a six digit number with a dash (i.e. 001-001). The first three numbers represent the facility identification code and the last three numbers represent the subject number. Subject numbers are assigned to all enrolled subjects at each site starting with 001 and continuing in order until the study ends.

**Subject Withdrawal** - Subjects will have the right to withdraw from the study at any time. If a subject withdraws from the study before all required data are collected, the data already collected will be used for data analysis. A Memo to File will be written explaining the circumstances and reason of the withdrawal and will be placed in the subjects study file. Notification of the change in status will be sent electronically to the lead PI. Being that this study is designed as a 'one time' encounter, withdrawal from the study is not anticipated and highly unlikely.



## SECTION 5. STUDY PROCEDURES

**Enrollment and Testing** – Once a patient has completed the consent process and met criteria eligibility, they may be enrolled in the study and tested. One Enrollment CRF (Appendix E) should be completed for each subject enrolled. This form is a site document and should be used as a self-check and for entering data on the Goniometry Data Submission Spreadsheet (Appendix G). The paper source document should be maintained in a secure location at the testing site and be accessible to the investigator for audits.

**The Enrollment CRF (Appendix E) should be completed as follows:**

1. The date of testing and Study ID# are noted. Subject age and gender are recorded.
2. The original size of burn is documented from information in the subject's medical record.
3. Ethnicity is selected as either "Non-Hispanic" or "Hispanic/ Latino." "Unknown" is used for any other response.
4. Race is select as "Caucasian," "Native Hawaiian/Pacific islander," "Asian," "African American," "American Indian/Alaska Native," or "Other." If the subject does not know their race, select "Unknown." If the subject does not report their race, select "Not Reported."
5. After completing photographs and SAGE diagram, (further described in this section) indicate completion on the Enrollment CRF. If photographs were not taken of the CFU of interest, log the reason.

This form is a source document and should be used for entering data on the Goniometry Data Submission Spreadsheet (Appendix G).

6. The person completing the Enrollment CRF signs and dates it when completed.

**Goniometry Paradigm Data Collection**  
**ENROLLMENT Case Report Form**  
**NOTE: Use ONE form only per patient**

Date: \_\_\_\_\_

Study ID: \_\_\_\_\_ (FACILITY#-SUBJECT#: e.g. 001-001)

Age (18-60): \_\_\_\_\_ Gender: ☐ Male (1) ☐ Female (2)

Date of original burn (mm-dd-year): \_\_\_\_\_

Size of original burn (%TBSA) \_\_\_\_\_

Ethnicity: ☐ Non-Hispanic (01) ☐ Hispanic/Latino (02) ☐ Unknown (03)

Race: ☐ Caucasian (01) ☐ Native Hawaiian/Pacific Islander (02) ☐ Asian (03)

☐ African American (04) ☐ American Indian/Alaska Native (05) ☐ Other (06)

☐ Unknown (07) ☐ Not Reported (08)

SAGE Diagram completed: ☐ Yes (1) ☐ No (2)

Photograph of area/CFU of interest taken: ☐ Yes (1) ☐ No (2)\*

If no, reason: \_\_\_\_\_

\* Optional for females with anterior trunk burns. If photos not taken, scar distribution on chest should be verified for SAGE diagram.

Signature of study team member completing CRF: \_\_\_\_\_

Date: \_\_\_\_\_

USAISR

**Photography of test sites** – If the subject agrees to photographs, use a digital camera to photograph the CFU area related to the designated contracture according to instructions in Appendix K. The photograph must be de-identified (i.e. no identifying subject information including full face photographs). Include in the photograph the entire area outlined in red on the instruction page for each contracture being measured. Example: Neck flexion contracture the photograph should be taken from mouth to hip bones including width of chest. Two photographs of each site should be taken. The photographs should be immediately downloaded into a secure folder located on a local computer and then securely sent via SAFE.

**Surface Area Graphic Evaluation (SAGE) Diagram** – Follow the steps in Appendix L to complete the electronic SAGE diagram for the subject found at:

**[https://www.sagediagram.com/sagegoni/sagecfu\\_login.php](https://www.sagediagram.com/sagegoni/sagecfu_login.php).**

1. Use the secure login previously assigned at the time of on-site training.
2. Complete a new diagram for each subject and include all of the areas being tested on one diagram.

3. When done diagramming, click the “Calculate tab” then the “Save tab” followed by the “Submit tab.”
4. A notification will appear in the upper center of the diagram indicating that the diagram has been successfully submitted to the goniometry study.
5. When the diagram is complete, it must be printed, signed and dated and stored in the subject’s study folder at the local site.

Depending on the procedures at the participating site, the completion of the SAGE diagram may happen in real time as the subject is being tested or may occur after the testing with reference to the photographs. The exact procedure can be determined at the local site. The PI will be able to access the data remotely.

SAGE - Surface Area Graphic Evaluation © 1987-2015

University of California-I

Patient GNI ID# 001-004 User Ingrid

Age 35 Kilos 0

Image n/a Jun 20, 20

Burn TBSA

	Antr%	Postr%
Head		
Neck		
Lt. Arm		
Lt. Forearm		
Lt. Hand		
Rt. Arm	01.77	
Rt. Forearm	00.00	
Rt. Hand		
Trunk	08.44	
Lt. Thigh		
Lt. Leg		
Lt. Foot		
Rt. Thigh		
Rt. Leg		
Rt. Foot		
Perineum		

Legend: Text, Partial, Deep, Grafted

Signature / Date

**Randomization** – The order of measurement of multiple sites will be randomized as well as the order of revised GM v. standard GM methods. The randomization table is a specially designed excel spreadsheet that automatically provides randomization. **Use of the Randomization Table (Appendix D) is follows.**

1. Indicate Y (yes) or N (no) for each of the motions in the first column based on the physical screening for inclusion of that particular area to the study data.

2. A response in the first column will trigger the “Eligibility Status” column to change color. “Y” = “Eligible” and green cell block color, “N” = “Non-Eligible” and red cell block color.
  3. If in the first column the subject’s body region is indicated as “Eligible,” then a randomization number is generated and automatically appears in the next column. If a particular body region is not to be included in the study, then the “Random Number” column will read as “NA” indicating this area is Not Accepted. The “Random Number” column is informational only and the researcher will not have to do anything with the information in this column.
  4. Depending on how many body regions are going to be measured, the “Body Region Order” column will indicate to the clinician the order in which to measure various body areas as indicated by a random numeral that is generated by the measurement sequence randomization. If an area is “Non-Eligible,” a “NA” will appear in this column.
  5. The “First GM Measurement” column will instruct the clinician as to which of the GM measurement positions to use first, either the Revised GM position or the Standard GM position.
- The notations from the last two columns are manually transferred to the Measurement Case Report Form (Appendix F).

Goniometry Measurement Randomization Table				
Is the Patient Eligible for GM Measurement in the Body Region?				
Body Region	Yes/No	Eligibility Status	Random Number	Body Region Order
Neck Extension	N	Non-Eligible	NA	NA
Shoulder Abduction	Y	Eligible	0.640613949	5
Shoulder Flexion	Y	Eligible	0.797848446	2
Elbow Flexion	N	Non-Eligible	NA	NA
Elbow Extension	N	Non-Eligible	NA	NA
Wrist Flexion	Y	Eligible	0.176257623	6
Wrist Extension	Y	Eligible	0.708131765	4
Knee Flexion	N	Non-Eligible	NA	NA
Knee Extension	N	Non-Eligible	NA	NA
Ankle Dorsiflexion	Y	Eligible	0.713390659	3
Ankle Plantarflexion	Y	Eligible	0.801876621	1
		First GM Measurement		
		Revised		
		Standard		

**Standard and Revised Goniometric Testing** – Measure the sites enrolled in the study according to the order defined by the randomization table. First measure the site with standard GM or revised GM positioning again according to the randomization table. When measuring, use Appendix C for written and pictorial reference of testing positioning, stabilization, goniometer

position and testing motion. Record the measurements for each site tested on the Measurement case report form (Appendix F). Laminated cards of the revised and standard goniometry positions also have been provided for ease of reference during the test session. Personnel who perform test measures must have had prior training on the standard GM and revised GM techniques.

**Data Collection** - Measurement data should be recorded on the Measurement CRF (Appendix F) as the subject is being tested. One measurement CRF should be completed PER area measured. There may be multiple Measurement CRFs associated with each Enrollment CRF (Appendix E) for each subject. **The Measurement CRF should be completed as follows.** The date that the measurements are taken and the Study ID # are noted. This is the six digit number with a dash (i.e. 001-001) that was assigned to the subject when enrolled. Place a check mark next to name of the motion being measured. **Only one motion should be checked per form.** If multiple motions are measured, additional Measurement CRFs should be used. In the "First Position Measured" box, select the box for which position was measured first according to the randomization table, standard GM or revised GM. After each measurement is taken, log the value in the appropriate box on the form according to if it is standard or revised and if it is measurement 1,2 or 3. Use the negative sign if applicable and use Appendix A for reference of normal ROM value ranges. If a subject is able/ unable to fully achieve the established body and adjacent joint test position, note 'yes' or 'no' for that measurement series and if the position of testing was different than the described position for standard GM or revised GM (Appendix C), then describe in the open area of the box how it was different and be specific. The researcher completing the measurements should sign the form upon completion. This form is a source document and should be used for entering data on the Goniometry Data Submission Spreadsheet (Appendix G). The paper document should be maintained in a secure location at the testing site and accessible to the investigator if needed for audits.

Goniometry Paradigm Data Collection MEASUREMENT Case Report Form				
NOTE: Use one form PER site tested (may be multiple forms per subject)				
Measurement Date: _____		Study ID: _____		Signature: _____
+ Burn scar goniometric measurement direction (check only one per form):				
<input type="checkbox"/> Neck extension (022000)	<input type="checkbox"/> Right elbow extension (042200)	<input type="checkbox"/> Right knee extension (201200)		
<input type="checkbox"/> Right shoulder abduction (032002)	<input type="checkbox"/> Left elbow extension (052200)	<input type="checkbox"/> Left knee extension (191200)		
<input type="checkbox"/> Left shoulder abduction (032001)	<input type="checkbox"/> Right elbow flexion (041200)	<input type="checkbox"/> Right knee flexion (202200)		
<input type="checkbox"/> Right shoulder flexion (031002)	<input type="checkbox"/> Left elbow flexion (051200)	<input type="checkbox"/> Left knee flexion (192200)		
<input type="checkbox"/> Left shoulder flexion (031001)	<input type="checkbox"/> Right wrist extension (042100)	<input type="checkbox"/> Right ankle plantarflexion (202300)		
<b>First Position Measured:</b>		<input type="checkbox"/> Left wrist extension (052100)	<input type="checkbox"/> Left ankle plantarflexion (192300)	
<input type="checkbox"/> Standard (1) <input type="checkbox"/> Revised (2)		<input type="checkbox"/> Right wrist flexion (041100)	<input type="checkbox"/> Right ankle dorsiflexion (201300)	
		<input type="checkbox"/> Left wrist flexion (051100)	<input type="checkbox"/> Left ankle dorsiflexion (191300)	
Goniometry Range of Motion Measurements (Degrees – use negative sign as applicable):				
Method	Measurement 1	Measurement 2	Measurement 3	Is subject able to attain full and proper position?
Standard (1) Measured first? <input type="checkbox"/>	°	°	°	Standard: <input type="checkbox"/> Yes (1) <input type="checkbox"/> No (2)
Revised (2) Measured first? <input type="checkbox"/>	°	°	°	Revised: <input type="checkbox"/> Yes (1) <input type="checkbox"/> No (2)
Deviation to described position:		Standard: Revised:		

**Electronic Goniometry Data Submission Spreadsheet** - Data from the Enrollment CRF (Appendix E) and each Measurement CRF (Appendix F) should be entered on the Goniometry Data Submission Spreadsheet (Appendix G) with care that all relevant fields are complete. Each column is labelled according to the categories on the CRFs and data should be entered horizontally in the top available row. The excel data spreadsheet will be transferred to the lead PI after each subject is tested utilizing the SAFE file exchange for storage in a password protected computer. One spreadsheet should be sent per subject. This is the data that will undergo audit and be used for analysis. Data will be checked for accuracy at the time of submission by the lead site PI.

**SAFE transfer of data** – Go to website: <https://safe.amrdec.army.mil/SAFE/> . Click on blue box under “Non-CAC Users”. Enter your name and your email address. Confirm your email address. Select “Browse” and find the Electronic Goniometry Data Submission Spreadsheet excel file. The excel file should have data from one subject only and the data should be de-identified. Next, select the de-identified photographs to send. Set the “Deletion Date” at the max “14 days from TODAY” and write a description of the file with subject # but no identifying information.

Version #1  
8 August 2015

For recipient, input [reg.l.richard.ctr@mail.mil](mailto:reg.l.richard.ctr@mail.mil) then select “add”. To send data, select “upload”. Please notify Reg Richard [reg.l.richard.ctr@mail.mil](mailto:reg.l.richard.ctr@mail.mil) and Ingrid Parry [iparry@ucdavis.edu](mailto:iparry@ucdavis.edu) in a separate email to inform them when data has been sent but DO NOT attach data to these emails. You will be sent an email from SAFE.team with a password you must use to verify your email before it can be sent.

## **SECTION 6. DATA MANAGEMENT**

**Clinical Data Management** – Data for this study will be collected on two source documents Enrollment CRF (Appendix E) and Measurement CRF (Appendix F) and transferred to electronic Goniometric Data Spreadsheet (Appendix G). Photographs will be taken as previously described and securely stored and transferred electronically. SAGE data will be collected directly on the secured, password protected website. The Goniometric Data Spreadsheet (Appendix G) and the photographs will be the only documents securely sent to the lead site via SAFE. All other documents will be stored locally in the subject's study folder and where they will be made accessible for possible audits. The lead site PI will have remote access to data entered in SAGE.

**Source Documentation** - Each subject must have a research study folder that is maintained at the participating site. The subjects' folders should only be identifiable by the Goniometry Study ID# assigned to the individual. The folders should be maintained in a secure and locked environment.

The subject study folder should contain:

- 1) Subject's signed Informed Consent
- 2) HIPAA forms
- 3) Signed enrollment CRF (Appendix E)
- 4) Signed measurement CRF (Appendix F) – one for EACH area of interest measured
- 5) A signed copy of the final SAGE diagram and CFU output for each contracted area measured
- 6) Any other documentation used to substantiate data entries, such as body burn percentages
- 7) Study correspondence related to subject
- 8) Documentation of reportable events (protocol deviations, adverse events)
- 9) Audit information (if applicable)

**Data Validation** – As the data is submitted to the lead site, it will be checked for accuracy by the lead site PI. Questions regarding data entry will be addressed and discussed directly between the lead PI and a participating facility representative listed on the site protocol.



## SECTION 7. STUDY COMPLETION

**Sample Size Estimation** – The number of subjects and ROM measurements anticipated from each participating center are shown in the table below. The estimated numbers are derived from reported activity at each facility. Enrollments per facility may differ than those estimated.

Facility	Anticipated number of enrollees x contracture sites
U. S. Army Institute of Surgical Research	$36 \times 2 = 72$
University of California – Davis	$24 \times 2 = 48$
University of Colorado	$10 \times 2 = 20$
University of Iowa	$17 \times 2 = 34$
Regions Hospital Burn Center	$12 \times 2 = 24$
University of North Carolina – Chapel Hill	$13 \times 2 = 26$
Louisiana State University – Shreveport	$13 \times 2 = 26$
Arkansas Children's Hospital	$18 \times 2 = 36$
John Hopkins Burn Center	$28 \times 2 = 56$

**Interim Analysis and Study Completion** - An interim analysis will be conducted after the first 163 measurements. If statistical significance is not reached for the entire group, then an additional 45 GM measurements will be recorded before a second interim analysis occurs. This process will continue an additional three times if needed to reach the maximum number of 341 comparative GM trials. If, at the first or a subsequent interim analyses (if required), statistical significance is achieved for the composite group, then sub-analyses of each individual joint direction will be performed. For any and all motions that reach statistical significance individually, data collection will cease for that motion at all study facilities. Data collection will resume at all other joint sites, and this process will continue for primary and secondary motions until either statistical significance is reached or the study time has ended. The PI will notify the participating site when to cease data collection for each specific motions and overall collection.

## **SECTION 8. STUDY COMPLIANCE**

**Risks of Harm** – This study is no greater than minimal risk. Research related risks include mild discomfort, possible soreness or separation of scar tissue. To reduce the potential risk when positioning and performing GM measurements, the subjects' tissue will be pre-conditioned (i.e. loosened up either by usual therapy provided during the course of non-study related treatment or formal tissue preconditioning). Throughout testing, the subject's tolerance will be assessed by verbally requesting feedback of subject discomfort.

**Reporting Adverse Events** – Any unexpected adverse events or problems should be reported to the local IRB per institutional policy. The lead site PI should be notified immediately. If an unexpected event or unanticipated problem occurs, the lead site PI will immediately notify all study personnel by electronic communication. If necessary, a core protocol amendment will be submitted to address the problem.

**Protocol Deviations** – Any deviation to the protocol requires reporting the lead PI with seven (7) business days by electronic notification and reported to the local IRB per institutional policy. If deemed necessary by the lead PI, a follow-up telephone may ensue to discuss the situation. A copy of any institutional documentation should be sent to the lead PI.

## **SECTION 9. POLICIES**

**Security of Files** – Research records including subject study folder and digital photographs will be maintained and stored at the participating site and lead site in accordance with local site policies and as stated in the protocol.

**Confidentiality** – Confidentiality of ongoing project work will be maintained at all participating sites.

**Privacy** - Data from all sites, concatenated by the lead PI will be presented as anonymous data. Thus when the results of the research are published or presented, no information will be included that would reveal the subjects' identity.

# Appendices

## Appendix A Minimum LOM and Normal Reference ROM

### Minimum Goniometry Joint ROM Contracture

Joint Motion	ROM Norm	ROM SD	ROM w/ Tolerance
Neck extension	50°	14°	34°
Shoulder abduction	180°	9°	162°
Shoulder flexion	170°	5°	157°
Elbow flexion	145°	6°	132°
Elbow extension	0°	5°	12°
Wrist flexion	75°	7°	65°
Wrist extension	70°	8°	59°
Knee flexion	135°	8°	120°
Knee extension	0°	2°	9°
Ankle dorsiflexion	16°	4°	11°
Ankle plantarflexion	45°	6°	37°

ROM = Range of Motion

SD = Standard Deviation

## Appendix B Validity Table

Revised Goniometry Measurement Criterion Validity						
				Gold Standard Measurement	Minimal Allowable Deviation	
				105	2	
Rate	Measurement			Mean	Pass/Fail	
r	1	2	3			
1	10	10	10	105.7	PASS	
	5	7	5			
2	10	10	10	106.3	PASS	
	7	8	4			
3	10	10	10	106.3	PASS	
	9	5	5			
4	10	11	10	106.3	PASS	
	5	0	4			
5	10	11	10	107.7	FAIL	
	2	4	7			
9	10	10	11	106.7	PASS	
	4	2	4			
7	10	10	11	109.0	FAIL	
	7	5	5			
8	10	10	11	108.7	FAIL	
	5	9	2			
9	10	11	10	109.7	FAIL	
	8	6	5			

## Appendix C Standard and Revised Goniometry Positions Protocol



### ANKLE PLANTARFLEXION

#### STANDARD POSITION

**Testing Position:** Subject sitting with knee flexed to 90 degrees with leg supported to mid-thigh, zero degrees ankle inversion/eversion.

**Stabilization:** Stabilize the tibia and fibula to prevent knee flexion and hip rotation.

**Goniometer Position:**

- Center of fulcrum of goniometer over the lateral aspect of the lateral malleolus.
- Proximal arm aligned with the midline of the fibula (using fibular head as reference).
- Distal arm aligned parallel to the lateral aspect of the fifth metatarsal.

**Testing Motion:** Passively plantarflex the foot by pushing downward on the dorsum of the subject's foot, avoiding inversion/ eversion.

**AMA normative value:** 45 degrees



### ANKLE PLANTARFLEXION

#### REVISED POSITION\*

**Testing Position:** Subject lying supine, knee fully extended, lower leg supported and heel free from mat, neutral hip rotation and zero degrees ankle inversion/eversion.

**Stabilization:** Stabilize the tibia and fibula to prevent hip rotation.

**Goniometer Position:**

- Center of fulcrum of goniometer over the lateral aspect of the lateral malleolus.
- Proximal arm aligned with the midline of the fibula (using fibular head as reference).
- Distal arm aligned parallel to the lateral aspect of the fifth metatarsal.

**Testing Motion:** Passively plantarflex the foot by pushing downward on the dorsum of the subject's foot, avoiding inversion/ eversion and hip rotation.



## **ANKLE DORSIFLEXION**

### **STANDARD POSITION**

**Testing Position:** Subject sitting with knee flexed to 90 degrees with leg supported to mid-thigh, zero degrees ankle inversion/eversion.

**Stabilization:** Stabilize the tibia and fibula to prevent knee motion and hip rotation.

**Goniometer Position:**

- Center of fulcrum of goniometer over the lateral aspect of the lateral malleolus.
- Proximal arm aligned with the midline of the fibula (using fibular head as reference).
- Distal arm aligned parallel to the lateral aspect of the fifth metatarsal.

**Testing Motion:** Passively dorsiflex the foot by pushing upward on the plantar surface of the foot, avoiding inversion/ eversion.

**AMA normative value:** 16 degrees



## **ANKLE DORSIFLEXION**

### **REVISED POSITION**

**Testing Position:** Subject lying supine, knee flexed 10 degrees with towel roll, lower leg supported and heel free from mat, neutral hip rotation and zero degrees ankle inversion/eversion.

**Stabilization:** Stabilize the tibia and fibula to prevent knee extension and hip rotation.

**Goniometer Position:**

- Center of fulcrum of goniometer over the lateral aspect of the lateral malleolus.
- Proximal arm aligned with the midline of the fibula (using fibular head as reference).
- Distal arm aligned parallel to the lateral aspect of the fifth metatarsal.

**Testing Motion:** Passively dorsiflex the foot by pushing upward on the plantar surface of the foot, avoiding inversion/ eversion and hip rotation.



## **KNEE FLEXION**

### **STANDARD POSITION**

**Testing Position:** Subject lying supine, hip flexed to 90 degrees, ankle relaxed, opposite leg extended and supported.

**Stabilization:** Stabilize the femur in 90 degrees hip flexion, preventing rotation, abduction or adduction of the hip.

**Goniometer Position:**

- Center of fulcrum of goniometer over the lateral epicondyle of the femur.
- Proximal arm aligned with the lateral midline of the femur (using greater trochanter for reference).
- Distal arm aligned with the lateral midline of the fibula (using the lateral malleolus and fibular head for reference).

**Testing Motion:** Hold the subject's lower leg in one hand, stabilizing the thigh at 90 degrees hip flexion with the other hand and passively move the foot toward the buttocks for knee flexion.

**AMA normative value:** 135 degrees



## **KNEE FLEXION**

### **REVISED POSITION**

**Testing Position:** Subject lying supine at the side edge of mat (for foot clearance when knee is flexed), hip flexed to 55 degrees and stabilized with foam wedge (may secure with strap), ankle relaxed, opposite leg extended.

**Stabilization:** Stabilize the thigh in place with hip flexed to 55 degrees, preventing rotation, abduction or adduction of the hip.

**Goniometer Position:**

- Center of fulcrum of goniometer over the lateral epicondyle of the femur.
- Proximal arm aligned with the lateral midline of the femur (using greater trochanter for reference).
- Distal arm aligned with the lateral midline of the fibula (using the lateral malleolus and fibular head for reference).

**Testing Motion:** Hold the subject's lower leg in one hand, stabilizing the thigh at 55 degrees hip flexion with the other hand and passively move the knee into flexion, allowing the foot to drape off the side of the plinth.



## **KNEE EXTENSION**

### **STANDARD POSITION**

**Testing Position:** Subject lying supine, towel roll under the ankle to allow the knee to extend as much as possible, ankle relaxed, opposite leg extended and supported.

**Stabilization:** Stabilize the femur to prevent rotation, abduction or adduction of the hip.

**Goniometer Position:**

- Center of fulcrum of goniometer over the lateral epicondyle of the femur.
- Proximal arm aligned with the lateral midline of the femur (using greater trochanter for reference).
- Distal arm aligned with the lateral midline of the fibula (using the lateral malleolus and fibular head for reference).

**Testing Motion:** Passively move the knee into extension.

**AMA normative value:** 0 degrees



## **KNEE EXTENSION**

### **REVISED POSITION**

**Testing Position:** Supine, hip flexed to 50 degrees with wedge supporting thigh posteriorly, ankle relaxed, opposite leg extended.

**Stabilization:** Stabilize the femur at 50 degrees hip flexion and prevent rotation, abduction or adduction of the hip.

**Goniometer Position:**

- Center of fulcrum of goniometer over the lateral epicondyle of the femur.
- Proximal arm aligned with the lateral midline of the femur (using greater trochanter for reference).
- Distal arm aligned with the lateral midline of the fibula (using the lateral malleolus and fibular head for reference).

**Testing Motion:** Support the subject's thigh with one hand and the foam block, stabilizing the hip at 50 degrees flexion. With the other hand, passively move the knee into extension by lifting the foot off of the plinth.



## **SHOULDER FLEXION**

### **STANDARD POSITION**

**Testing Position:** Subject lying supine, with knees flexed, 0 degrees shoulder abduction, adduction and rotation, elbow in extension, palm of the hand facing inward to the body.

**Stabilization:** Stabilize the trunk and ribs from lifting off examination table.

**Goniometer Position:**

- Center of fulcrum of goniometer over the lateral aspect of the greater tubercle of the humerus.
- Proximal arm parallel to the midaxillary line of the thorax.
- Distal arm aligned with the lateral midline of the humerus.

**Testing Motion:** Passively flex the shoulder by lifting the arm off of the exam table and bringing the hand up above subject's head.

**AMA normative value:** 170 degrees



## **SHOULDER FLEXION**

### **REVISED POSITION\***

**Testing Position:** Subject lying supine, with knees and hips extended, 0 degrees shoulder abduction, adduction and rotation, elbow in extension, palm of the hand facing inward to the body.

**Stabilization:** Stabilize the trunk and ribs from lifting off examination table.

**Goniometer Position:**

- Center of fulcrum of goniometer over the lateral aspect of the greater tubercle of the humerus.
- Proximal arm parallel to the midaxillary line of the thorax.
- Distal arm aligned with the lateral midline of the humerus.

**Testing Motion:** Passively flex the shoulder by lifting the arm off of the exam table and bringing the hand up above subject's head.





## SHOULDER ABDUCTION

### STANDARD POSITION

**Testing Position:** Subject lying supine, with knees flexed, shoulder in lateral rotation, 0 degrees shoulder flexion and extension, elbow in extension, palm facing anteriorly.

**Stabilization:** Stabilize the trunk and ribs to prevent lateral trunk flexion.

**Goniometer Position:**

- Center of fulcrum of goniometer close to the anterior aspect of the acromion process.
- Proximal arm parallel to the midline of the anterior aspect of the sternum.
- Distal arm aligned with the anterior midline of the humerus.

**Testing Motion:** Passively abduct the shoulder by moving the humerus laterally away from the subject's trunk. Maintain the upper extremity in lateral rotation and neutral flexion/ extension.

**AMA normative value:** 180 degrees



## SHOUDLER ABDUCTION

### REVISED POSITION

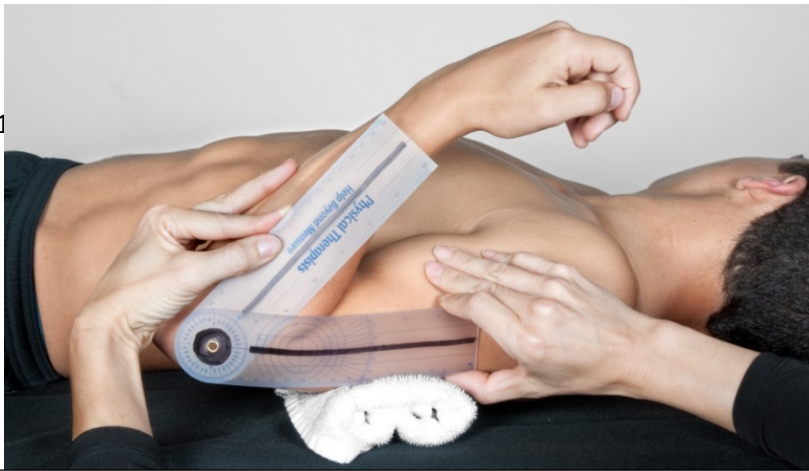
**Testing Position:** Subject lying supine, with knees and hips extended, shoulder in lateral rotation, 0 degrees shoulder flexion and extension, elbow in extension, palm facing anteriorly.

**Stabilization:** Stabilize the trunk and ribs to prevent lateral trunk flexion.

**Goniometer Position:**

- Center of fulcrum of goniometer close to the anterior aspect of the acromion process.
- Proximal arm parallel to the midline of the anterior aspect of the sternum.
- Distal arm aligned with the anterior midline of the humerus.

**Testing Motion:** Passively abduct the shoulder by moving the humerus laterally away from the subject's trunk. Maintain the upper extremity in lateral rotation and neutral flexion/ extension.



## **ELBOW FLEXION**

### **STANDARD POSITION**

**Testing Position:** Subject lying supine, with shoulder in zero degrees of flex/extension/abduction, arm along the side of body, a towel roll under the humerus, forearm supination, and wrist neutral.

**Stabilization:** Stabilize the humerus to prevent flexion of the shoulder.

**Goniometer Position:**

- Center of fulcrum of goniometer over the lateral epicondyle of the humerus.
- Proximal arm aligned with the lateral midline of the humerus (center of acromion for reference).
- Distal arm aligned with the midline of the radius (radial styloid process for reference).

**Testing Motion:** Passively flex the elbow by moving the hand toward the shoulder, maintaining supination.

**AMA normative value:** 145 degrees



## **ELBOW FLEXION**

### **REVISED POSITION**

**Testing Position:** Subject sitting with the shoulder flexed to 90 degrees and supported on a surface, forearm supination, and wrist neutral.

**Stabilization:** Stabilize the humerus to prevent flexion of the shoulder greater than 90 degrees.

**Goniometer Position:**

- Center of fulcrum of goniometer over the lateral epicondyle of the humerus.
- Proximal arm aligned with the lateral midline of the humerus.
- Distal arm aligned with the midline of the radius (radial styloid process for reference).

**Testing Motion:** Passively flex the elbow by moving the hand toward the shoulder, maintaining supination.



## **ELBOW EXTENSION**

### **STANDARD POSITION**

**Testing Position:** Subject lying supine, with shoulder in zero degrees of flex/extension/abduction, arm along the side of body, a towel roll under the humerus to allow for full elbow extension, forearm supination, and wrist neutral.

**Stabilization:** Stabilize the humeral head to prevent forward translation or extension of the shoulder.

**Goniometer Position:**

- Center of fulcrum of goniometer over the lateral epicondyle of the humerus.
- Proximal arm aligned with the lateral midline of the humerus (center of acromion for reference).
- Distal arm aligned with the midline of the radius (radial styloid process for reference).

**Testing Motion:** Passively extend the elbow by moving the hand toward the examining table, maintaining supination.

**AMA normative value:** 0 degrees



## **ELBOW EXTENSION**

### **REVISED POSITION**

**Testing Position:** Subject sitting supported in recline on a wedge or the lifted portion of a plinth, shoulder extended 50 degrees off side of surface, forearm supination, wrist neutral.

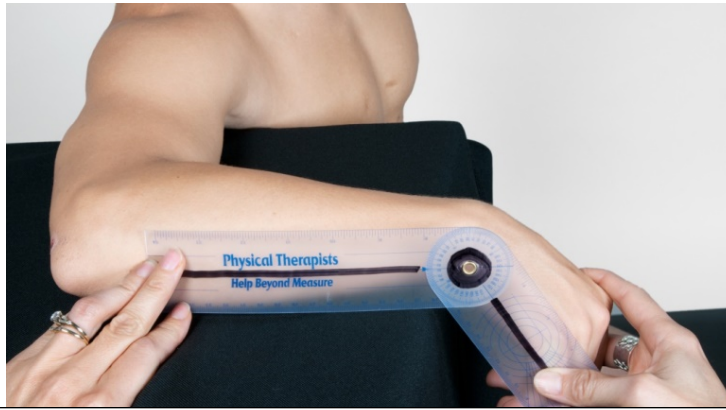
**Stabilization:** Stabilize the humeral head to prevent forward translation and to maintain 50 degrees extension at shoulder.

**Goniometer Position:**

- Center of fulcrum of goniometer over the lateral epicondyle of the humerus.
- Proximal arm aligned with the lateral midline of the humerus (center of acromion for reference).
- Distal arm aligned with the midline of the radius (radial styloid process for reference).

**Testing Motion:** Passively extend the elbow by moving the hand downward, clearing the side of the examining table, maintaining supination.





## **WRIST FLEXION**

### **STANDARD POSITION**

**Testing Position:** Subject sitting next to a supporting surface with the shoulder abducted to 90 degrees, elbow flexed to 90 degrees, forearm midway between supination and pronation so that palm of hand faces the ground. Rest forearm on the supporting surface, hand off end of surface. Avoid radial / ulnar deviation.

**Stabilization:** Stabilize the radius and ulna to prevent supination or pronation and motion of the elbow.

**Goniometer Position:**

- Center of fulcrum of goniometer over the lateral aspect of the wrist over the triquetrum.
- Proximal arm aligned with the lateral midline of the ulna (using the olecranon and ulnar styloid process for reference).
- Distal arm aligned with the lateral midline of the fifth metacarpal (do not use soft tissue of hypothenar eminence for reference).

**Testing Motion:** Passively flex the wrist by pushing the dorsal surface of the third metacarpal, moving the hand toward the floor.

**AMA normative value:** 75 degrees



## **WRIST FLEXION**

### **REVISED POSITION**

**Testing Position:** Subject sitting next to a supporting surface with the shoulder flexed to 90 degrees, elbow extended, forearm pronated so that palm of hand faces the ground. Arm supported on surface, wrist and hand off end of surface, fingers 'relaxed closed' (make a fist, then relax fingers).

**Stabilization:** Stabilize the radius and ulna to prevent supination or pronation and motion of the elbow.

**Goniometer Position:**

- Center of fulcrum of goniometer over the lateral aspect of the wrist over the triquetrum.
- Proximal arm aligned with the lateral midline of the ulna.
- Distal arm aligned with the lateral midline of the fifth metacarpal (do not use soft tissue of hypothenar eminence for reference).

**Testing Motion:** Passively flex the wrist by pushing the dorsal surface of the third metacarpal, moving the hand toward the floor.



## **WRIST EXTENSION**

### **STANDARD POSITION**

**Testing Position:** Subject sitting next to a supporting surface with the shoulder abducted to 90 degrees, elbow flexed to 90 degrees, forearm midway between supination and pronation so that palm of hand faces the ground. Rest forearm on the supporting surface, hand off end of surface. Avoid radial/ ulnar deviation.

**Stabilization:** Stabilize the radius and ulna to prevent supination or pronation and motion of the elbow.

**Goniometer Position:**

- Center of fulcrum of goniometer over the lateral aspect of the wrist over the triquetrum.
- Proximal arm aligned with the lateral midline of the ulna (using the olecranon and ulnar styloid process for reference).
- Distal arm aligned with the lateral midline of the fifth metacarpal (do not use soft tissue of hypothenar eminence for reference).

**Testing Motion:** Passively extend the wrist by pushing evenly across the palmar surface of the metacarpals, moving the hand in a dorsal direction toward the ceiling.

**AMA normative value:** 70 degrees



## **WRIST EXTENSION**

### **REVISED POSITION**

**Testing Position:** Subject sitting next to a supporting surface with the shoulder flexed to 90 degrees, elbow extended, forearm pronated so that palm of hand faces the ground. Arm supported on surface, wrist and hand off end of surface, fingers 'relaxed open' (actively extend fingers, then relax).

**Stabilization:** Stabilize the radius and ulna to prevent supination or pronation and motion of the elbow.

**Goniometer Position:**

- Center of fulcrum of goniometer over the lateral aspect of the wrist over the triquetrum.
- Proximal arm aligned with the lateral midline of the ulna.
- Distal arm aligned with the lateral midline of the fifth metacarpal (do not use soft tissue of hypothenar eminence for reference).

**Testing Motion:** Passively extend the wrist by pushing evenly across the palmar surface of the metacarpals, moving the hand in a dorsal direction toward the ceiling.





## **NECK EXTENSION**

### **STANDARD POSITION**

**Testing Position:** Sitting upright with thoracic and lumbar spine supported, cervical spine should have 0 degrees of rotation or lateral flexion, lips approximated.

**Stabilization:** Stabilize the shoulder girdle to prevent extension of the thoracic and lumbar spine (done with patient support, chair support or a strap may be used).

**Goniometer Position:**

- Center of fulcrum of goniometer over the external auditory meatus.
- Proximal arm aligned perpendicular or parallel to the ground.
- Distal arm aligned to the base of nares. (May use tongue depressor in the mouth if alignment with nares not possible).

**Testing Motion:** Put one hand on the back of the subject's head. Hold the patient's chin with the other hand. Passively extend cervical spine.

**AMA normative value:** 50 degrees

## Appendix D: Randomization Table

<i>Goniometry Measurement Randomization Table</i>					
Is the Patient Eligible for GM Measurement in the Body Region?					
Body Region	Yes/No	Eligibility Status	Random Number	Body Region Order	First GM Measurement
Neck Extension	N	Non-Eligible	NA	NA	NA
Shoulder Abduction	Y	Eligible	0.447878517	4	Standard
Shoulder Flexion	N	Non-Eligible	NA	NA	NA
Elbow Flexion	N	Non-Eligible	NA	NA	NA
Elbow Extension	N	Non-Eligible	NA	NA	NA
Wrist Flexion	Y	Eligible	0.656294653	3	Revised
Wrist Extension	Y	Eligible	0.02860599	5	Revised
Knee Flexion	N	Non-Eligible	NA	NA	NA
Knee Extension	N	Non-Eligible	NA	NA	NA
Ankle Dorsiflexion	Y	Eligible	0.831524794	2	Revised
Ankle Plantarflexion	Y	Eligible	0.884784562	1	Revised

## Appendix E Enrollment Case Report Form

**Goniometry Paradigm Data Collection**  
**ENROLLMENT Case Report Form**  
**NOTE: Use ONE form only per subject**

Date: \_\_\_\_\_

Study ID: \_\_\_\_\_ (FACILITY#-SUBJECT#; e.g. 001-001)

Age (18-60): \_\_\_\_\_ Gender: ☐ Male (1) ☐ Female (2)

Date of original burn (mm-dd-year) \_\_\_\_\_

Size of original burn (%TBSA) \_\_\_\_\_

Ethnicity: ☐ Non-Hispanic (01) ☐ Hispanic/Latino (02) ☐ Unknown (03)

Race: ☐ Caucasian (01) ☐ Native Hawaiian/Pacific Islander (02) ☐ Asian (03)

☐ African American (04) ☐ American Indian/Alaska Native (05) ☐ Other (06)

☐ Unknown (07) ☐ Not Reported (08)

SAGE Diagram completed: ☐ Yes (1) ☐ No (2)

Photograph of area/CFU of interest taken: ☐ Yes (1) ☐ No (2)\*

If no, reason: \_\_\_\_\_

\* Optional for females with anterior trunk burns. If photos not taken, scar distribution on chest should be verified for SAGE diagram.

Signature of study team member completing CRF: \_\_\_\_\_

Date: \_\_\_\_\_

## Appendix F: Measurement Case Report Form

### Goniometry Paradigm Data Collection MEASUREMENT Case Report Form NOTE: Use one form PER site tested (may be multiple forms per subject)

Measurement Date: \_\_\_\_\_ Study ID: \_\_\_\_\_ Signature: \_\_\_\_\_

☐ Burn scar goniometric measurement direction (check only one per form):

<input type="checkbox"/> Neck extension (022000)	<input type="checkbox"/> Right elbow extension (042200)	<input type="checkbox"/> Right knee extension (201200)
<input type="checkbox"/> Right shoulder abduction (032002)	<input type="checkbox"/> Left elbow extension (052200)	<input type="checkbox"/> Left knee extension (191200)
<input type="checkbox"/> Left shoulder abduction (032001)	<input type="checkbox"/> Right elbow flexion (041200)	<input type="checkbox"/> Right knee flexion (202200)
<input type="checkbox"/> Right shoulder flexion (031002)	<input type="checkbox"/> Left elbow flexion (051200)	<input type="checkbox"/> Left knee flexion (192200)
<input type="checkbox"/> Left shoulder flexion (031001)	<input type="checkbox"/> Right wrist extension (042100)	<input type="checkbox"/> Right ankle plantarflexion (202300)
	<input type="checkbox"/> Left wrist extension (052100)	<input type="checkbox"/> Left ankle plantarflexion (192300)
	<input type="checkbox"/> Right wrist flexion (041100)	<input type="checkbox"/> Right ankle dorsiflexion (201300)
	<input type="checkbox"/> Left wrist flexion (051100)	<input type="checkbox"/> Left ankle dorsiflexion (191300)

First Position Measured:

☐ Standard (1) ☐ Revised (2)

Goniometry Range of Motion Measurements (Degrees – use negative sign as applicable):

Method	Measurement 1	Measurement 2	Measurement 3	Is subject able to attain full and proper position?
Standard (1) Measured first? <input type="checkbox"/>	°	°	°	Standard: <input type="checkbox"/> Yes (1) <input type="checkbox"/> No (2)
Revised (2) Measured first? <input type="checkbox"/>	°	°	°	Revised: <input type="checkbox"/> Yes (1) <input type="checkbox"/> No (2)
Deviation to described position:	Standard:			
	Revised:			

## Appendix G: Goniometric Data Submission Spreadsheet

INSTRUCTIONS:										
A	B	C	D	E	F	G	H	I	J	K
<b>INSTRUCTIONS:</b>										
Please use only the described format for data entry										
All codes MUST be numeric unless noted with *										
ONE form per subject (all measurements included)	1 digit code with a dash (FACILITY-SUBJECT) (e.g. 001-001)	1 digit in year	1-Male; 2-Female	MM/DD/YY	MM/DD/YY	digit only	1-Hispanic/Latino; 2-Hispanic/Latino; 3-Unknown	1-Caucasian; 2-Asian; 3-Hispanic/Latino; 4-Black; 5-Other; 6-Unknown; 7-Not reported	Body side (R/L), joint and direction of movement* (e.g. Left Elbow Extension)	1 digit OFU code (e.g. 052200)
	STUDY ID	AGE	GENDER	MEASUREMENT DATE	DATE OF BURN	ORIGINAL TBSA	ETHNICITY	RACE	MOVEMENT MEASURED*	CODE
Enter Data this Row ➡										

INSTRUCTIONS:												
J	K	L	M	N	O	P	Q	R	S	T	U	V
<b>GONIOMETRIC SITE 1</b>												
<b>STANDARD POSITION SITE 1</b>												
<b>REVISED POSITION SITE 1</b>												
Body side (R/L), joint and direction of movement* (e.g. Left Elbow Extension)	1 digit OFU code (e.g. 052200)	1-Standard measured flex; 2-Revised measured flex	Positive or negative number in degrees			1-year, 2-yr	Write in deviation to partition	Positive or negative number in degrees			1-year, 2-yr	Write in deviation to partition
MOVEMENT MEASURED*	CODE	MEASUREMENT ORDER	S MEASUREMENT 1	S MEASUREMENT 2	S MEASUREMENT 3	S POSITION/ACHIEVED	S DEVIATION*	R MEASUREMENT 1	R MEASUREMENT 2	R MEASUREMENT 3	R POSITION/ACHIEVED	R DEVIATION*

Version 1 06AUG2015

Appendix H			
<i>(This form should be kept at the local site and destroyed at completion of the Goniometry Study)</i>			
<b>Goniometry Study Eligibility Log</b>			
	<b>Inclusion Criteria</b>		<b>Exclusion Criteria</b>
	18 through 60 years of age		< 18 years or > 60 years of age
	Burn scar contracture associated with a primary or secondary area of interest		Joint(s) LOM due to soft tissue restriction other than burn scar tissue as the primary limiting tissue
	Minimum loss of motion (LOM) at joint of interest per Appendix A		Acute pain, as expressed by the subject, emanating from scar tissue preventing full available passive ROM
	Presence of a burn scar contracture as the principle soft tissue limiting joint ROM		LOM principally associated with open wound within CFU area of interest
			Joint ROM less than minimum listed in Appendix A
			Patients with neurologic, muscular or skeletal condition affecting a joint of interest, e.g. spasticity, arthritis, history of joint dislocation
			Patients with a medical history or diagnosis of fibromyalgia or dermatologic condition such as psoriasis, lupus, scleroderma
			Patients that have a LOM associated with a joint area of interest that has had a surgically-placed tissue flap.
In order to be eligible for this study the patient must meet all of the inclusion criteria and none of the exclusion criteria			
<b>Screen Date</b>	<b>Name</b>		<b>Study ID#</b>

**Appendix I: Recruitment Flier**

**Research Study Participants Needed**

**A Goniometry Paradigm Shift to Measure Burn Scar Contracture  
in Burn Patients**

We are conducting a research study to determine the best way to measure limited range of motion in joints (elbows, knees, etc.) affected by a burn scar contracture.

To participate, you must have limited motion caused by a burn scar at the neck, shoulder, elbow, wrist, knee or ankle joints.

Your commitment: To have your joint with limited movement measured three times in two different positions by a burn center clinician. Your scar area will be photographed. If you have more than one scar area, this process will be repeated for as many of the areas that you allow. The anticipated amount of time added to your clinic visit or rehab session would be approximately 10 minutes for each area.

Men and women between the ages of 18 and 60 are invited to participate.

If interested, please call:

[Study team member(s) (xxx) xxx-xxxx

[Name of Burn Center]

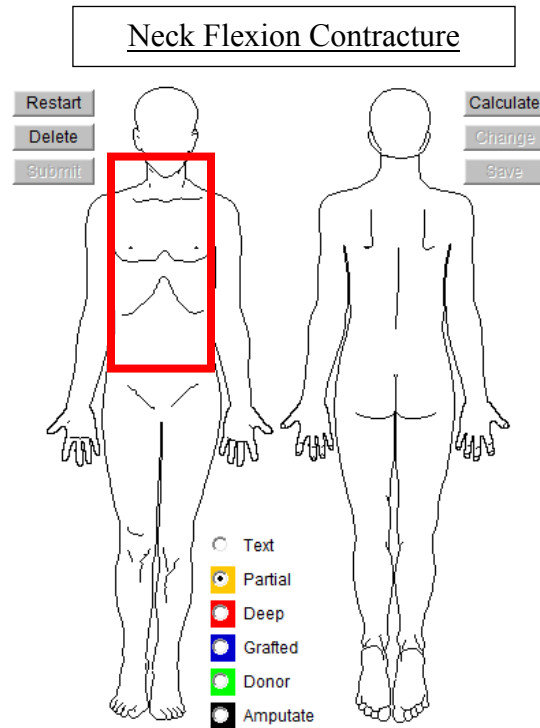
## Appendix J: Primary and Secondary Motions

Joints	Scar Contracture	Range of Motion	Primary	Secondary
Neck	Flexion	Extension	■	
Shoulder	Adduction	Abduction	■	
Shoulder	Extension	Flexion	■	
Elbow	Extension	Flexion		■
Elbow	Flexion	Extension	■	
Wrist	Extension	Flexion		■
Wrist	Flexion	Extension	■	
Knee	Extension	Flexion		■
Knee	Flexion	Extension	■	
Ankle	Plantarflexion	Dorsiflexion	■	
Ankle	Dorsiflexion	Plantarflexion		■

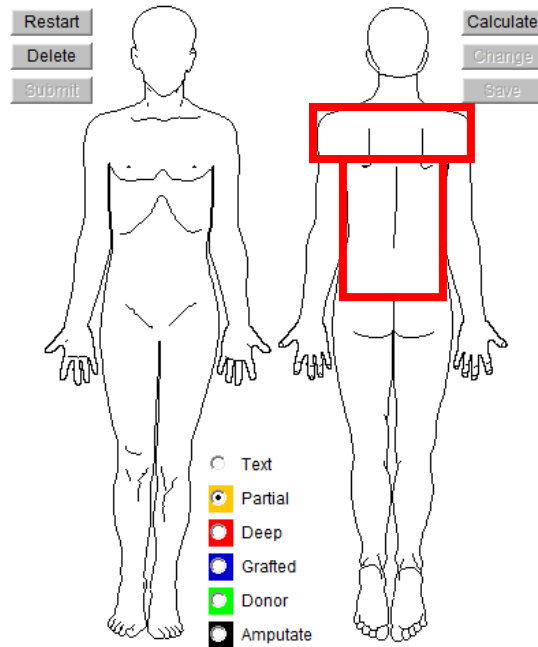


## Appendix K: Photograph Areas for CFU Identification

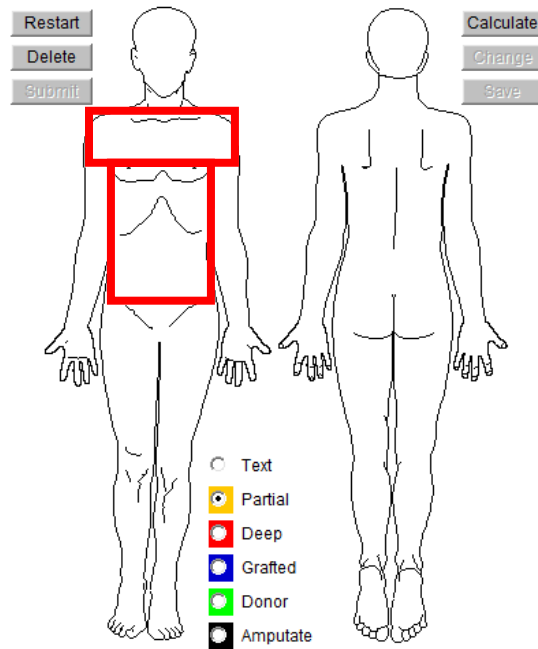
### Goniometry Study CFU Photographic Areas



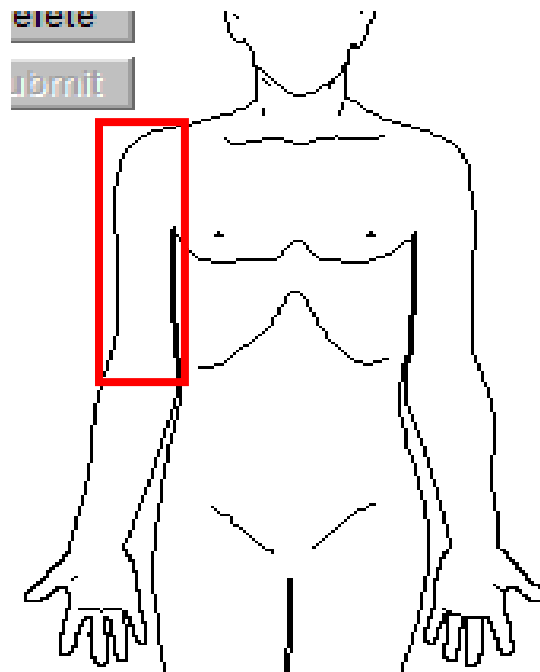
### Shoulder Extension Contracture



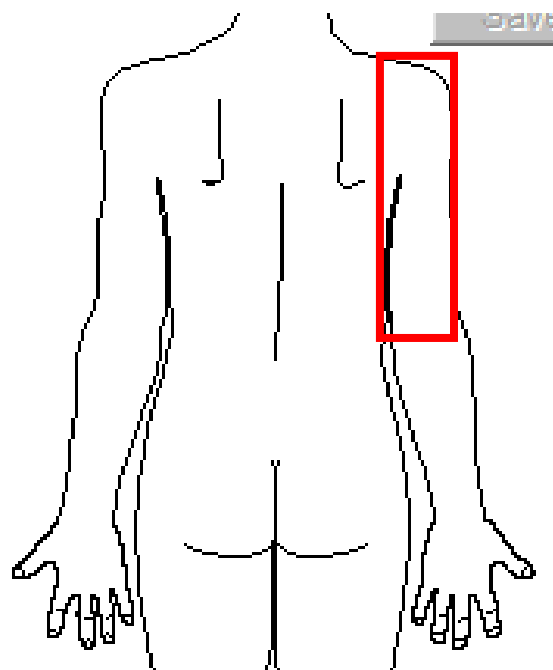
### Shoulder Adduction Contracture



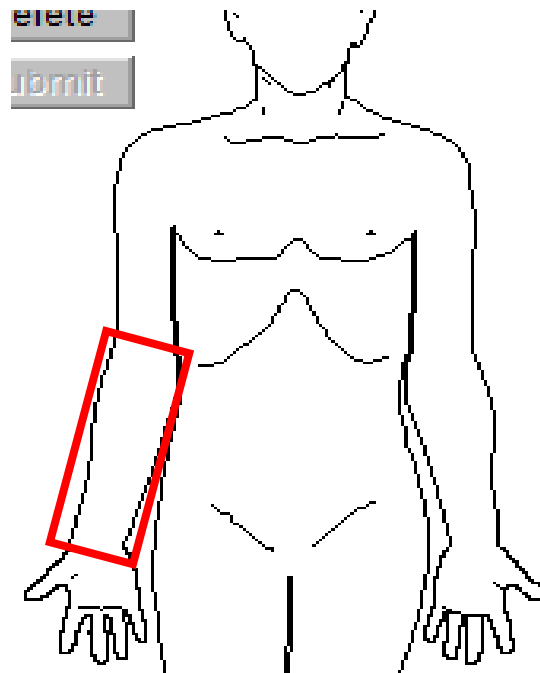
Elbow Flexion Contracture



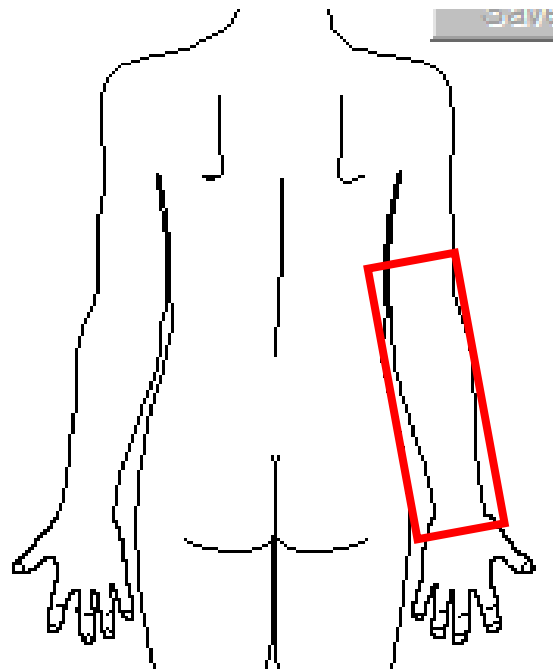
Elbow Extension Contracture



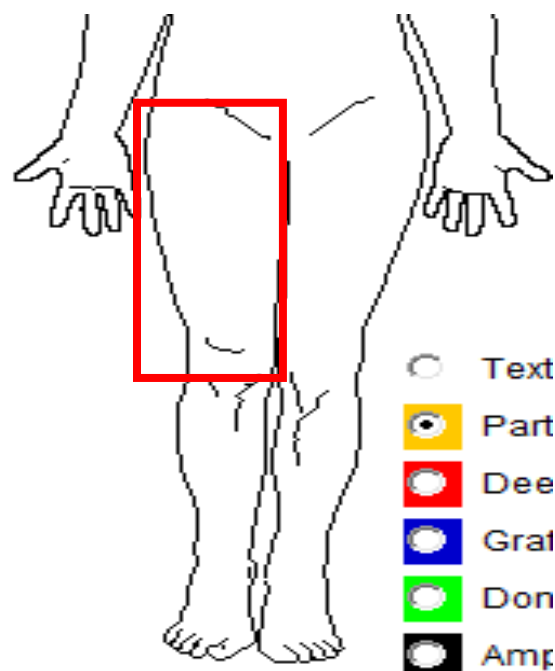
Wrist Flexion Contracture



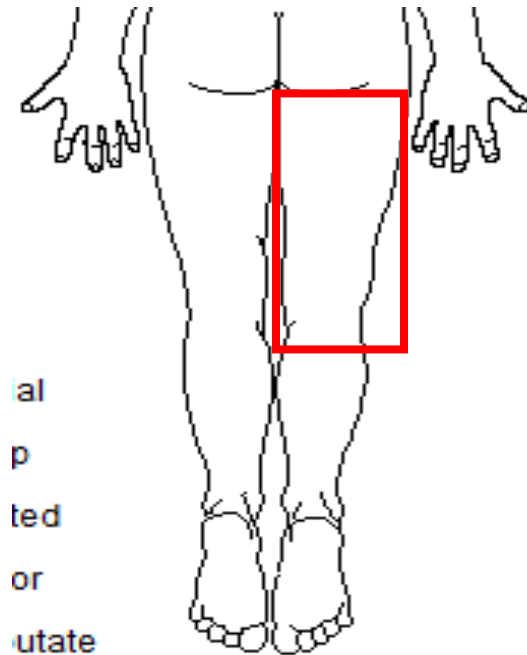
Wrist Extension Contracture



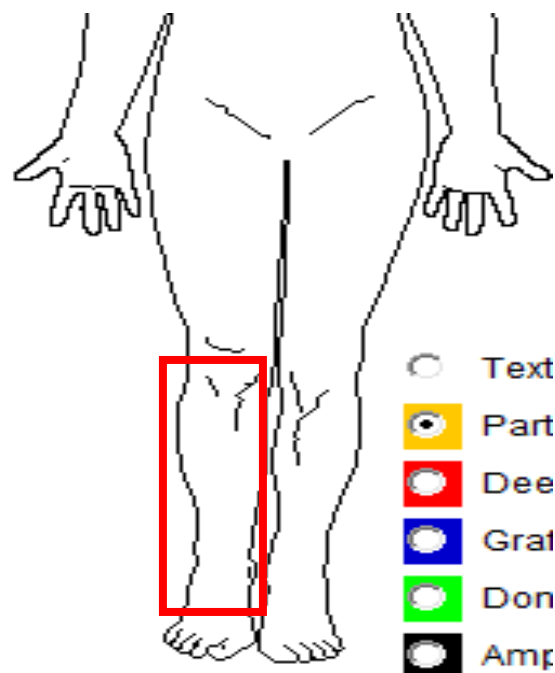
Knee Extension Contracture



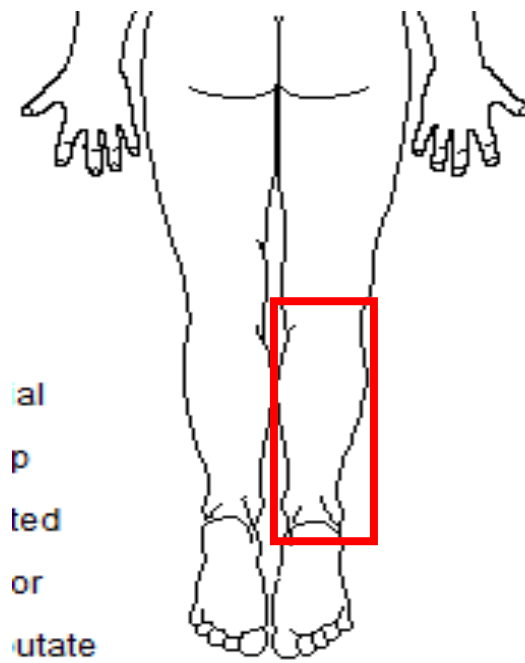
Knee Flexion Contracture



Ankle Dorsiflexion Contracture



Ankle Plantarflexion Contracture



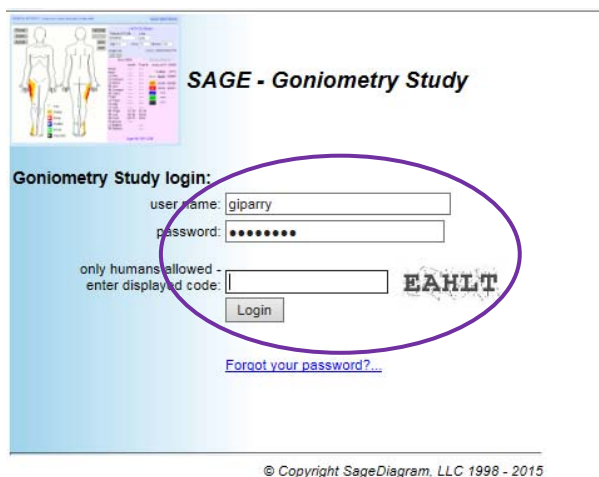
## Appendix L: SAGE Procedures

**Accessing SAGE Burn Body Diagram Program** (Mouse or roller ball needed for application)

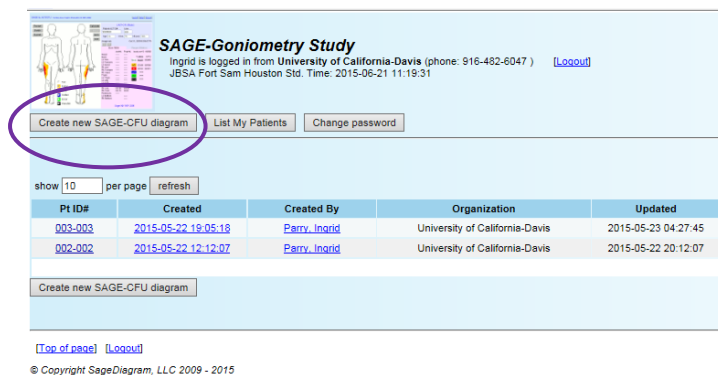
Click on the internet link [https://www.sagediagram.com/sagegoni/sagecfu\\_login.php](https://www.sagediagram.com/sagegoni/sagecfu_login.php) and a secure login page will appear:

Enter your **User Name** and **Password** as previously established.

Enter the Cryptic Code (Note: this code changes with each view of this screen) and click 'Login'



To create a **NEW DIAGRAM**, click "Create new SAGE-CFU diagram"



Pt ID#	Created	Created By	Organization	Updated
003-003	2015-05-22 19:05:18	Perry, Ingrid	University of California-Davis	2015-05-23 04:27:45
002-002	2015-05-22 12:12:07	Perry, Ingrid	University of California-Davis	2015-05-22 20:12:07

Type in the subject's **Study ID#** in the box labelled "Patient GNI ID#" on new diagram.

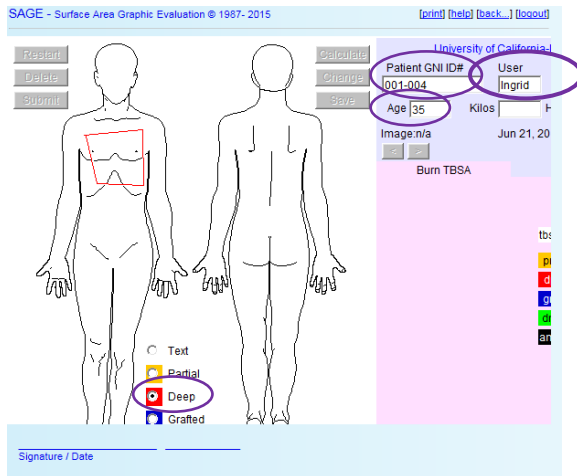
ENTER **Name** of person inputting the information in **User** box (if not automatically populated)

ENTER Patient **Age** by highlighting the default 18, deleting and re-typing unless this is the patient's age

Completing the Burn Body Diagram for each studied site:



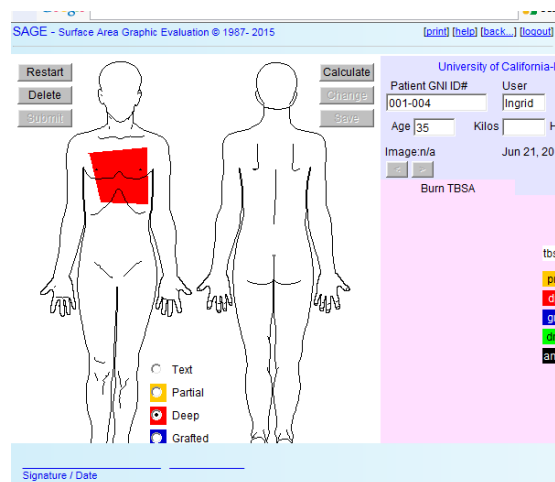
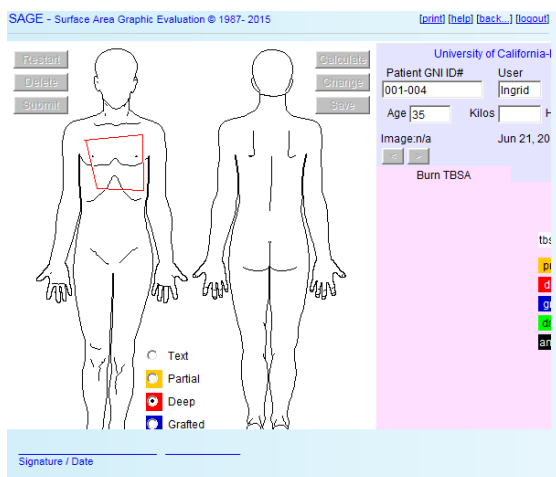
Select “Deep” from the **Color Palette (Red)** at the base of the screen. Disregard the other selections as depth of burn or grafted is not relevant to this study.



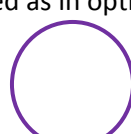
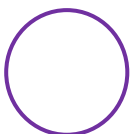
There are four (4) primary methods to outline a burn area involved in the in the CFU for the site of interested:

Option 1: Place cursor on body diagram in margin area of burn. ‘Click’ and hold depressed LEFT mouse button to outline a burn area returning to original beginning cursor position; release Left button and **immediately** RIGHT click mouse to fill-in the outlined area.

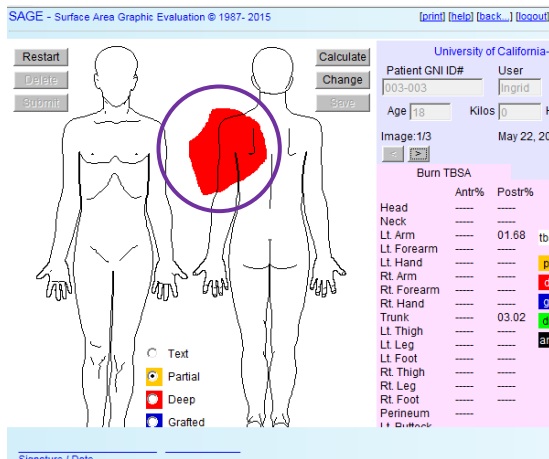
Option 2: Position cursor on body diagram. Click, release Left button in succession to ‘draw’ point-to-point areas of burn, returning to the start. RIGHT click mouse at end to fill-in outlined area.



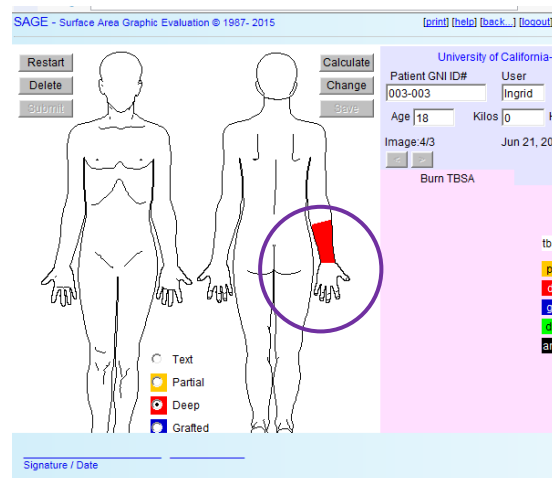
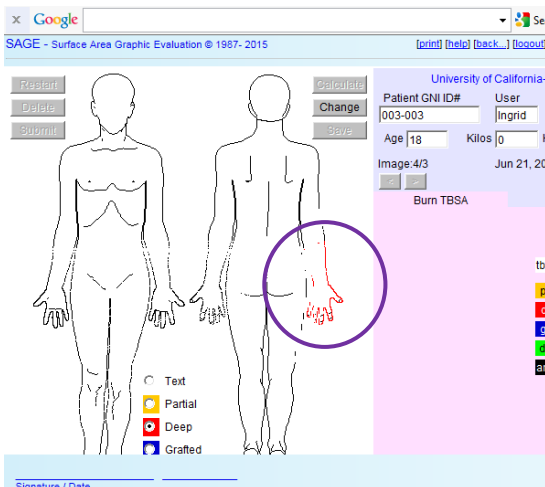
Option 3: To capture a large area, proceed as in option 1, however you can ‘draw



outside the lines' of the body diagram and the erroneous area will not be figured into the cutaneous functional unit area calculation.



Option 4: To highlight a large distal area, place cursor on a perimeter line of body diagram (must be on the diagram and not outside of the lines) at proximal edge of burn area to highlight. LEFT click and release the mouse button. Draw line across body segment. LEFT click again. Depress the "t" key on the keyboard (a cross-hair symbol appears). Using the cross-hair and without depressing a button, re-trace the horizontal line back to the original start point. Click the LEFT mouse button to outline the area. RIGHT click the mouse button to fill-in the entire area below the line.  
NOTE: Because this study does not include hand and/or fingers, these areas will not fill in.



To **DELETE** a burn area, **first** click the **Delete** key in the upper left corner of the screen and then click on the area to be removed.

When all diagramming is complete, select the "Calculate" tab. The individual percent burn of each body area for both anterior and posterior surfaces will be displayed.

When you are satisfied with the burn drawing, click the **'Save'** tab (or **'Resave'** tab if more than one drawing was created) to store the information. To submit the diagram to the study, click the **Submit** tab.

SAGE - Surface Area Graphic Evaluation © 1987- 2015 [print] [help] [back...] [logout]

University of California-I

Restart  
Delete  
Submit

Calculate  
Change  
Re-save

Patient GNI ID# 003-003 User Ingrid  
Age 18 Kilos 0  
Image 4/3 Jun 21, 20

Burn TBSA

	Antr%	Postr%	
Head	-----	-----	
Neck	-----	-----	
Lt. Arm	-----	-----	tb
Lt. Forearm	-----	-----	P
Lt. Hand	-----	-----	C
Rt. Arm	-----	-----	C
Rt. Forearm	-----	00.94	S
Rt. Hand	-----	-----	C
Trunk	-----	-----	
Lt. Thigh	-----	-----	
Lt. Leg	-----	-----	
Lt. Foot	-----	-----	
Rt. Thigh	-----	-----	
Rt. Leg	-----	-----	
Rt. Foot	-----	-----	
Perineum	-----	-----	
Lt. Buttock	-----	-----	

Signature / Date

**TEXT** Function allows you to add notes to diagram. Select **Text** button. Place cursor on body diagram where you want to place a text note. Left double-click the mouse and a Text Box appears. Type in the information desired at blinking cursor. Select "OK" and text appears on diagram and text box disappears. To return to typed text on diagram, left double click on a word and text box reappears. To remove text, highlight the text in the text box field, push keyboard 'Delete' button, select Text Box 'OK' button.

To access **EXISTING DIAGRAM**, click on "List my patients," then select the desired patient from the "Pt ID#" column.

SAGE-Goniometry Study  
Ingrid is logged in from University of California-Davis (phone: 916-482-6047 ) [Logout]  
JBSA Fort Sam Houston Std. Time: 2015-06-21 11:19:31

Create new SAGE-CPU diagram List My Patients Change password

show 10 per page refresh

Pt ID#	Created	Created By	Organization	Updated
003-003	2015-05-22 19:05:18	Perry, Ingrid	University of California-Davis	2015-05-23 04:27:45
002-002	2015-05-22 12:12:07	Perry, Ingrid	University of California-Davis	2015-05-22 20:12:07

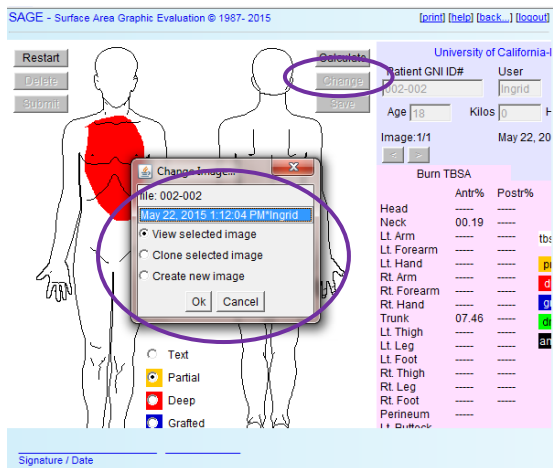
Create new SAGE-CPU diagram

[Top of page] [Logout]

© Copyright SageDiagram, LLC 2009 - 2015

To **VIEW OR CHANGE A DIAGRAM**, select the patient diagram you wish to view or change. Click on the "Change" tab on the upper right. A window will appear with three options: view, clone or create. To **VIEW DIAGRAM**, select the radio button for view and then select the file (date and time created) that you would like to view. No changes can be made from this selection. To **CHANGE DIAGRAM**, select "Clone" if you would like to make additions to the existing diagram. This will save as a new file with the added changes. Select "Create new diagram" if you would like to start with a blank diagram. Each file will be saved for the patient when "Calculate" and "Re-save" are selected.

Version #1  
8 August 2015



The final submitted SAGE diagram must be printed and signed and dated at the bottom of the form. The diagram will be stored with the subject's record material at the local site.

## October 2015

### Site Status

	Geneva contract	CRADA agreement	Local IRB approval	Secondary HRPO approval	Onsite Training
ISR	X	-	X	In progress	-
UCD	X	X	submitted		Oct 7/8
UOI	X	X	In progress		
LSU		X	In progress		
ARK	X	X	X	In progress	Oct 15
HOP			submitted		
REG			In progress		
UNC			In progress		
UOC			submitted		

### Enrollment Status

Count of	ISR	UCD	UOI	LSU	ARK	HOP	REG	UNC	UOC	TOTAL
<b>Neck Extension</b>										
<b>Shoulder Abduction</b>										
<b>Shoulder Flexion</b>										
<b>Elbow Extension</b>										
Elbow Flexion										
<b>Wrist Extension</b>										
Wrist Flexion										
<b>Knee Extension</b>										
Knee Flexion										
Plantarflexion										
<b>Ankle Dorsiflexion</b>										
<b>TOTAL</b>										

	Primary Sites	Secondary Sites	Total
ISR			
UCD			
UOI			
LSU			
ARK			
HOP			
REG			
UNC			
UOC			
<b>Total</b>			

## Goniometry Paradigm Study Training Session Checklist

Facility: \_\_\_\_\_

Date: \_\_\_\_\_

### Topics Covered:

- ☐ Review protocol process
- ☐ Review of Inclusion/Exclusion Criteria
- ☐ Review Screening Log
- ☐ Review Randomization Table
- ☐ Review submission of Case Report Forms & practice completion
- ☐ Subject/Study folder contents\*
- ☐ Protocol Deviation Process
- ☐ Completion of SAGE Diagram
  - ☐ Entering subject into system
  - ☐ Diagram shape – body map
  - ☐ 4 ways to diagram (Start/End; Point-to-Point; Outside the lines; Trace function)
  - ☐ Expanded diagrams (not used)
  - ☐ Duplicating diagrams
  - ☐ Submitting information
  - ☐ Retrieving diagram and information
  - ☐ Practice diagramming & printing
- ☐ Review and demonstrate subject positioning
  - ☐ Subject set-up for Elbow Extension
- ☐ Submitting data via SAFE
- ☐ Submitting Invoices for Data Remuneration
- ☐ Photography check

I acknowledge Goniometry Study training and all the above points have been reviewed and discussed in detail and to my satisfaction.

---

Goniometry Site Training Contact (Print)

---

Goniometry Study Representative (Print)

---

Goniometry Site Training Contact (Sign)

---

Goniometry Study Representative (Sign)

\*Subject folder contents:

- 1) Approval letter from Site's IRB and secondary HRPO
- 2) Protocol – most recent Core and Site Specific Addendum (Keep previous versions)
- 3) HIPAA – current stamped. One for each translation (Keep previous versions)
- 4) Consents – current stamped. One for each translation (Keep previous versions)
- 5) Amendments – Most recent signed copy with supporting documents and approval Memo
- 6) Reportable events – Individual AE/SAE reports and current AE/SAE log. Plus acknowledgments.
- 7) Continuing reviews
- 8) Case Report Forms
- 9) SAGE diagram & CFUs
- 10) Manual of Operating Procedures
- 11) Communication/Correspondence – emails, documentation of phone calls, notes on resolutions, instructions/requests from PI/IRB, etc.
- 12) Miscellaneous – CVs, CITIs, COIs